DATED 30 August 2023

THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE ACTING AS PART OF THE CROWN THROUGH THE UK HEALTH SECURITY AGENCY **(1)**

and

SEQIRUS UK LIMITED **(2)**

AGREEMENT

for the reservation of manufacturing capacity and production and supply of influenza pandemic specific vaccine during a pandemic

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THIS AGREEMENT is made on 30 August 2023

BETWEEN:

(1) **The Secretary of State for Health and Social Care** acting as part of the Crown through the UK Health Security Agency and whose principal office is 10 South Colonnade, Canary Wharf, London E14 5EA ("**Authority**"); and

(2) **Seqirus UK Limited** registered in England and Wales with company number 09614642 and whose registered office is Point, 29 Market Street, Maidenhead, Berkshire, England, SL6 8AA ("**Supplier**").

BACKGROUND:

A The Authority wishes to ensure that it has access to pandemic influenza vaccine in the event of a Pandemic (as defined below).

B The Supplier holds a Marketing Authorisation covering the UK (GB/NI) for a Pandemic Preparedness Vaccine for Adults. The Supplier holds a Marketing Authorisation covering the UK (GB/NI) for a Pandemic Preparedness Vaccine for Prophylaxis of influenza in an officially declared pandemic situation. Redacted Under FOIA Section 43(2), Commercial Interests

C The Authority wishes and the Supplier has agreed to reserve certain manufacturing capacity for production and supply of pandemic influenza vaccine in the event of a Pandemic on the terms of this Agreement.

D In the event of a Pandemic, should the Authority place an order in accordance with this Agreement, the Supplier has agreed to supply pandemic influenza vaccine subject to the terms of this Agreement.

IT IS AGREED as follows:

1. INTERPRETATION

1.1. In this Agreement unless the context otherwise requires the following words and expressions shall have the following meanings:

Words and Expressions	**Meaning**
Administering Entity	means any body administering the Product including all Health Service Bodies;
Agreement	means this Agreement including the attached Schedules;
Alternative Release Methodology	means the alternative release methodology set out in Schedule 11;
Anti-Slavery Policy	shall have the meaning given in Clause 33.2.2;

Words and Expressions	Meaning
Authorised Agent	means any authorised agent appointed by the Authority as notified to the Supplier in writing;
Batch	means a quantity of Product that is identified by a unique code by the Supplier and can be isolated from all other quantities of Product. "Batch" will also apply to Bulk Vaccine and to batches of components of the vaccine where the Product is delivered to the Supplier's customers without combining such components;
Bulk Vaccine	means vaccine that has been manufactured to the production process stage immediately prior to any formulation activities;
Business Continuity Event	means any event or issue that could impact on the operations of the Supplier and its ability to supply the Product including a Pandemic and any ForceMajeure event;
Business Continuity Plan	means the Supplier's business continuity plan which includes continuity during a Business Continuity Event and an executive summary of the current such plan is attached at Schedule 9. For the avoidance of doubt, the Supplier's Business Continuity Plan may be contained in more than one document;
Business Day	means a day (other than a Saturday, Sunday or public holiday) on which banks in the City of London are ordinarily open for the transaction of normal banking business;
Change Control Process	means the process set out in Schedule 10;
Codes of Practice	shall have the meaning referred to in Clause 20.1.2.6;
Commercially Reasonable Endeavours	means a reasonable degree of effort to accomplish a given task having regard to the size and financial resources of the Party upon whom such obligation falls and the current industry standards applicable to such Party Redacted Under FOIA Section 43(2), Commercial Interests

Words and Expressions	Meaning
Commercially Sensitive Information	means the commercially sensitive and/or confidential information listed in Schedule 17, which the Supplier has indicated to the Authority should not be disclosed;
Competent Authority	means the competent authority of an EEA state which has granted in relation to the Product a Marketing Authorisation, Manufacturing Licence and/or other licence in accordance with applicable Law;
Confidential Information	means information, data and material of any nature which either Party may receive or obtain in connection with the operation of the Agreement and: (i) which comprises Personal Data or Sensitive Personal Data (as defined in the Data Protection Legislation) or (in the case of the Authority) which relates to any patient or their treatment or medical history; or (ii) which relates to the status or impact of any Pandemic; or (iii) the release of which is likely to prejudice the commercial interests of the Authority and/or the Supplier respectively, including the contents of any Order and related information such as delivery locations; or (iv) which is a trade secret;
Contract Price	the price exclusive of Value Added Tax that is payable to the Supplier by the Authority under the Agreement for the full and proper performance by the Supplier of its obligations under the Agreement, as set out in Schedule 3;
Contract Review Meeting	means meetings held in accordance with Clause 10 and Part A of Schedule 8;
Contract Year	means any calendar year commencing on the Effective Date or any anniversary of the Effective Date during the Term;

Words and Expressions	Meaning
Contracting Authority	means any contracting authority as defined in regulation 2(1) of the Public Contracts Regulations 2015 (SI 2015/102), other than the Authority;
Contracts Finder	means the online government portal which allows suppliers to search for information about contracts worth over £10,000 (excluding VAT) as prescribed by Part 4 of the Public Contract Regulations 2015 (SI 2015/102) or such equivalent portal as may be prescribed by applicable Law from time to time;
CPI	means the UK Consumer Prices Index (or any successor index);
Crown Dependency	means the Bailiwicks of Jersey and Guernsey, and the Isle of Man;
Data Protection Legislation	all applicable data protection and privacy legislation in force from time to time in the UK including the UK GDPR; the Data Protection Act 2018 (c.12) (and regulations made thereunder) and the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426) and the Guidance and codes of practice issued by the Information Commissioner or other relevant regulatory authority and applicable to a Party;
Declaration of a Pandemic	means: (i) a public announcement by the World Health Organization that the spread of an influenza virus is classified as a Pandemic; or (ii) the occurrence of any one of the Specific Criteria applicable to the Pandemic Phase of the WHO Classification System;
Defective Product	means Products or any part of Products found not to conform to or not to have been produced in accordance with Good Manufacturing Practice, the Specification and/or the Marketing Authorisation, or otherwise to have failed to conform to the requirements of this Agreement relating to the safety and efficacy of the Product (including such requirements set out in Clauses

Words and Expressions	Meaning
	7.4.6, 7.16, 13.1 and 13.2);
Delivery Schedule	means the delivery schedule for the Product to be delivered by the Supplier to the Authority being: (i) the delivery schedule completed in accordance with the provisions set out in Schedule 5; (ii) any delivery schedule for Orders agreed by the Parties in accordance with Clauses 4.9, 4.10, 5.3 and/or 7.2.3; (iii) any delivery schedule for additional Doses of the Product agreed by the Parties in accordance with Clause 5.11 (completed in accordance with the provisions set out in Schedule 5); and (iv) any revised delivery schedule agreed in accordance with Clause 9.4;
Devolved Administration	means the governments of Scotland, Northern Ireland and/or Wales, and any other administration to which responsibility for public health in part of the United Kingdom is devolved;
Direct Sub-contractors	means, notwithstanding the definition of Sub-contract, those suppliers of the Supplier who make a material contribution to the manufacturing, storage or distribution of the Product under this Agreement;
Directive 2001/83	means Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (and any implementing, amended and/or successor legislation applicable to the UK or any part of it);
Dose	means 0.5 ml of Product;

Words and Expressions	Meaning
DOTAS	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 (c.26) and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 (c.26) and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012 (SI 2012/1868) made under s.132A Social Security Administration Act 1992 (c.5);
Effective Date	means the 1 September 2023;
Environmental Regulations	shall have the meaning referred to in Clause 20.1.2.6;
EU References	shall have the meaning given to the term in Clause 1.2.5;
European Public Assessment Report	shall have the meaning given to such term in Article 13(3) of Regulation (EC) No 726/2004;
Exit Day	shall have the meaning in the European Union (Withdrawal) Act 2018 (c.16);
First Wave Purchasers	means those entities that intend to purchase or purchase a Pandemic Specific Vaccine during the first wave of a Pandemic;
FOIA	shall have the meaning referred to in Clause 20.1.2.6;
Force Majeure	means any of the following insofar as the relevant event is beyond the control of the Party in question: (i) failure of the Seed Virus to grow to produce greater than Redacted Under FOIA Section 43(2), Commercial Interests;

Words and Expressions	Meaning
	(ii) if the World Health Organization or Licensing Authority declare that the virus causing the Pandemic has mutated or has undergone reassortment to such an extent that the Product will not be or is unlikely to be effective (such Force Majeure event to apply only in respect of the manufacture and supply of the Product affected by such mutation and/or reassortment);
	(iii) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Agreement;
	(iv) acts of terrorism;
	(v) acts of God;
	(vi) flood, storm or other like natural disasters;
	(vii) fire;
	(viii) prolonged unavailability of public utilities to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning;
	(ix) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, Laws or procedures (including such Laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment;
	(x) compliance with any local Law or governmental order, rule, regulation or direction that could not have been reasonably foreseen;
	(xi) industrial action which affects the supply of the Product, but which is not

Words and Expressions	Meaning
	confined to the workforce of the Supplier or the Supplier's sites or the workforce of any Sub-contractor or Sub-contractor sites used to undertake any obligations of the Supplier under this Agreement;
	(xii) pandemic or epidemic to the extent that the Supplier has taken all steps set out within its Business Continuity Plan for the Product (including ensuring adequate stockpiling of raw materials and packaging components within the UK) but unavailability of staff, utilities or raw materials at its suppliers (for whom no alternative is reasonably available) render such Business Continuity Plan and/or stockpiling efforts unsuccessful;
	(xiii) non-availability of raw materials provided that such non-availability does not result from any failure of the Supplier to meet its obligations under this Agreement to build up and maintain a stockpile of raw materials in the UK and/or to have in place robust arrangements for the supply of such materials;
	(xiv) to the extent that the Supplier has taken all steps to ensure UK Manufacture and a resilient supply of Product to the UK, the prevention by a government or other competent authority of the land transport of Products across a national border provided that this shall only be a Force Majeure event to the extent that air transport to the relevant destination is not available; or
	(xv) to the extent that UK production of the Product is compromised due to a Force Majeure event and the Supplier is prevented from using the Supplier's other production locations outside the UK for business continuity purposes, provided that this shall only be a Force Majeure event to the extent such prevention is also due to a Force Majeure event and the Supplier has otherwise met its obligations in relation to ensuring UK Manufacture,

Words and Expressions	Meaning
	but excluding, for the avoidance of doubt, any event or other consequence arising as a result of or in connection with: (i) the withdrawal of the United Kingdom from the European Union; or (ii) the COVID-19 pandemic, except for circumstances caused by or related to the COVID-19 pandemic which are changes in applicable Law and/or governmental guidance which mean that the Products cannot be provided as set out in this Agreement (in all material respects) without such Laws and/or government guidance being breached, or if the Supplier can reasonably demonstrate that despite all reasonable endeavours, it is unable to secure non-COVID-19 infected personnel to provide the Products due to the levels of COVID-19 infections in the population of the United Kingdom;
Fraud	means any offence under Laws creating offences in respect of fraudulent acts or at common law in respect of fraudulent acts in relation to this Agreement or defrauding or attempting to defraud or conspiring to defraud the Crown;
Full UK Population Coverage	means that the Marketing Authorisation covers all of the population groups referred to in Recital B;
General Anti-Abuse Rule	means: (iii) the legislation in Part 5 of the Finance Act 2013 (c.29); and (iv) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;
Good Industry Practice	means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier engaged in the manufacture and/or supply of goods similar to the

Words and Expressions	Meaning
	Products under the same or similar circumstances as those applicable to this Agreement, including in accordance with any codes of practice published by relevant trade associations;
Good Manufacturing Practice	shall have the meaning set out in in the Human Medicines Regulations 2012 (SI 2012/1916);
Guidance	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Products, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Authority, NHS England, a Licensing Authority or the European Commission (in each case to the extent applicable to the UK), the Care Quality Commission, the World Health Organization and/or any other regulator or competent body;
Halifax Abuse Principle	means the principle explained in the CJEU Case C-255/02 Halifax and others;
Health Service Body	means: (i) the Department of Health and Social Care and all divisions and agencies thereof, and any independent NHS board or similar body that may be established including regional agencies of such board; (ii) a GP (being a medical practitioner providing general medical services or personal medical services under the National Health Service Act 2006 (c.41) (whether operating in partnership with others or not)); (iii) health service bodies referred to in section 9 of the National Health Service Act 2006 (c.41); (iv) the Secretary of State for Health and Social Care; (v) any care trust as defined in section 77 of the National Health Service Act 2006

Words and Expressions	Meaning
	(c.41);
	(vi) any NHS foundation trust listed in the register of NHS foundation trusts maintained pursuant to section 39 of the National Health Service Act 2006 (c.41);
	(vii) any body providing similar or equivalent services to any of the above in any area of the United Kingdom or any body replacing the same or replacing any of the above mentioned bodies, including any bodies established pursuant to the Health and Social Care Act 2012 (c.7); or
	(viii) any statutory successor to any of the above;
Initial Phase	means the period from the Effective Date until the Declaration of a Pandemic;
Intellectual Property Rights	means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs;
Invitation to Participate in Dialogue	means the Invitation to Participate in Dialogue published on 9 March 2022 by the Authority;
Invitation to Submit Final Tenders	means the Invitation to Submit Final Tenders despatched on 11 October 2022 to the Supplier by the Authority;
KPIs	means the key performance indicators as set out in Schedule 6;
Law	means any applicable legal requirements including, without limitation:
	(i) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales;
	(ii) to the extent binding under UK law, any applicable European Union obligation,

Words and Expressions	Meaning
	directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument); (iii) to the extent in force in the UK, any enforceable community right within the meaning of section 2(1) European Communities Act 1972 (c.68); (iv) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; (v) requirements set by any regulatory body as applicable in England and Wales; (vi) any relevant code of practice as applicable in England and Wales; and (vii) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (i) to (vi) above);
Licensing Authority	means the MHRA, the European Medicines Agency or other Competent Authority as the case may be (in the case of the European Medicines Agency or other Competent Authority, to the extent that any Marketing Authorisation, Manufacturing Licence and/or other relevant licence(s) issued by such entity is valid in Northern Ireland);
Loss Costs	means, to the extent that the Authority and/or Administering Entity and/or Devolved Administration has taken all reasonable steps to mitigate such losses, the following losses incurred by the Authority and/or Administering Entity and/or Devolved Administration: (i) all costs in connection with receiving and storing Defective Products; (ii) where the Defective Product has been despatched by or on behalf of the

Words and Expressions	Meaning
	Authority and/or Devolved Administration, the costs of dispatching and recalling the Defective Product; (iii) all wasted administrative and personnel costs of the Authority and/or any Administering Entity and/or Devolved Administration relating to a Defective Product; (iv) where individuals are required to be given further treatments of the Product or a suitable alternative because their initial course was a Defective Product, the costs of providing such further treatments of the Product or a suitable alternative to such individuals; (v) all costs in excess of the price paid or payable by the Authority for Defective Product incurred in sourcing alternative products from third parties; (vi) all costs associated with advising, screening, testing, treating or otherwise providing healthcare to patients in relation to a Defective Product; and (vii) any direct costs or direct losses incurred by the Authority and/or any Administering Entity and/or Devolved Administration resulting from the termination of this Agreement in the circumstances referred to in Clause 16.3. For the avoidance of doubt: (a) any Rejected Products or Products subject to a Requirement To Recall shall be deemed Defective Products for the purposes of this definition of Loss Costs; and (b) the requirement on the Authority and/or Administering Entity and/or Devolved Administration to have taken all reasonable steps to mitigate the losses set out under (i) through (vii) herein means that Loss Cost will cover no such item under (i) through (vii) to the extent they are attributable to a Defective Product if such Defective Product ought to have been discovered by the Authority's inspections in accordance with Clause 8.2 or is attributable to the Authority's and/or Administering Entity's and/or Devolved Administration's or any of its or their Authorised

Words and Expressions	Meaning
	Agent's handling of the Product;
Manufacturing Commitment	means the commitment made by the Supplier guaranteeing capacity for production and supply of the Total Allocated Volume in accordance with the Delivery Schedule in the event of a Pandemic;
Manufacturing Facilities	means the location(s) of the Supplier's manufacturing processes for the Product, and "Manufacturing Facility" shall mean any such location. Details of such locations as at the Effective Date are set out in Schedule 7;
Manufacturing Licence	means manufacturing licence number MIA 18532 granted by the Licensing Authority as amended or varied by the Licensing Authority from time to time;
Marketing Authorisation	means marketing authorisation numbers PLGB 47991/0011 (UK) and EU/1/09/577/004 (EU) respectively granted by the Licensing Authority as amended or varied by the Licensing Authority from time to time, including by a Variation of the Marketing Authorisation;
Material Sub-contractors	means, notwithstanding the definition of Sub-contract, those entities holding the Marketing Authorisation, manufacturing the bulk antigen, filling, packing and/or releasing the Product as set forth in Schedule 18;
MHRA	means the Medicines and Healthcare products Regulatory Agency;
Modern Slavery Helpline	means the modern slavery helpline phone number on 08000 121 700 or the online reporting tool which can be found online https://www.modernslaveryhelpline.org/
NIMAR	means the Northern Ireland MHRA Authorised Route;
Occasion of Tax Non-Compliance	means: (i) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1

Words and Expressions	Meaning
	October 2012 that is found on or after 1 April 2013 to be incorrect as a result of: a. Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; or b. the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and / or (ii) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 that gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date, or to a civil penalty for fraud or evasion;
Offer	means the offer submitted by the Supplier in response to the Invitation to Submit Final Tenders;
OMCL	means an Official Medicines Control Laboratory;
Order	means an order for the Product placed in accordance with this Agreement;
Original Purchase Price	means, for each material or service, the same price as that for which such materials and services were purchased for the manufacturing of the Volume;
Pandemic	means any period of time in respect of which the 'Pandemic Phase' alert pursuant to the Revised WHO Classification System applies, or such other categorisation the World Health Organization may give to an influenza pandemic from time to time, and announcement by the WHO of the new pandemic virus strain;

Words and Expressions	Meaning
Pandemic Preparedness Fee	means an annual fee due from the Authority to the Supplier as set out in Schedule 3;
Pandemic Preparedness Vaccine	means a vaccine that has been developed for a specific type of marketing authorisation by the Licensing Authority before a Pandemic occurs (that used to be known as 'mock up' vaccine). Pandemic Preparedness Vaccines normally contain a strain of bird flu virus (for example A/H5N1) that few people in the world have been exposed to and that could potentially cause a Pandemic. The vaccines are tested to determine whether they will protect people against the virus strain that they contain. In the event of a Pandemic, once the virus strain causing the Pandemic is identified, the manufacturer can include this strain in the authorised Pandemic Preparedness Vaccine and apply to the Licensing Authority for the vaccine to be authorised as a 'final' Pandemic Specific Vaccine;
Pandemic Specific Vaccine	means the specific vaccine authorised by the Licensing Authority during a Pandemic, based on the manufacturer's Pandemic Preparedness Vaccine in a Redacted Under FOIA Section 43(2), Commercial Interests using the Pandemic virus;
Party	means the Authority or the Supplier as appropriate, and "**Parties**" means both the Authority and the Supplier;
Performance Monitoring Report	means the "Performance Monitoring Report" as defined in Schedule 6;
Personal Data	means personal data as defined in the Data Protection Legislation;
Preparatory Activities	means those activities set out in Schedule 1;
Preparatory Pandemic Work	means all activities to be carried out by the Supplier prior to the commencement of manufacture of the Product including: (i) creating the cell lines or acquiring sufficient quantity of eggs, as appropriate, to grow the Seed Virus; (ii) preparing the laboratory facilities to

Words and Expressions	Meaning
	commence initial virus propagation once the Seed Virus is received;
	(iii) the initial growth of the Seed Virus;
	(iv) preparation of possible Alternative Release Methodology and research into the development and use of synthetic virus seeds;
	(v) fully cooperating with the reference laboratories and/or regulatory laboratories in relation to the development of the Reagent necessary for the manufacture of the Product;
	(vi) providing all other assistance and cooperation requested by the World Health Organization and the World Health Organization reference laboratories and the World Health Organization essential regulatory laboratories;
	(vii) undertaking all work associated with the application for a Variation of the Marketing Authorisation;
	(viii) liaison and full cooperation with the relevant Licensing Authority;
	(ix) purchasing of all materials necessary for the manufacture of the Product where not already stockpiled in accordance with this Agreement; and
	(x) implementing all third party contracts necessary for the manufacture of the Product;
Preparedness Phase	means:
	(i) the Initial Phase; and/or
	(ii) any period during the Term following the completion of delivery of Product under all Orders in respect of a specific Pandemic until the earlier of the Declaration of a Pandemic in respect of a subsequent Pandemic or the expiry or

Words and Expressions	Meaning
	termination of this Agreement;
Product	means the Pandemic Specific Vaccine as further specified in the Marketing Authorisation;
Publishable Performance Information	means any of the information in the Performance Monitoring Report which does not constitute Commercially Sensitive Information;
Quarter	means each period of three months ending on 31 March, 30 June, 30 September and 31 December (and Quarterly means once each Quarter);
Reagent	means the reagent used to quantify the antigen levels as expressed as the concentration of haemagglutinin (HA) in influenza vaccines using the single radial diffusion (SRD) test;
Reconciliation	means the invoice reconciliation process to be applied at the end of supply under an Order as described in Clause 14;
Regulation 726/2004	means Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (and any amended and/or successor legislation applicable to the UK or any part of it);
Rejected Product	means any Doses of Product rejected by the Authority for any or all of the reasons as set out in Clause 8.3;
Relevant Tax Authority	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;
Request for Information	means a request for information disclosure under the FOIA, the Codes of Practice or the Environmental Regulations;
Requirement to Recall	has the meaning set out in Clause 8.12;

Words and Expressions	Meaning
Reserved Capacity	means Redacted Under FOIA Section 43(2), Commercial Interests;
Revised WHO Classification System	means the WHO Classification System at Schedule 13 with a revised alert phase to include sub-phases A, B and C which are not defined by WHO. These sub-phases better describe for the purposes of this Agreement when pre-Pandemic manufacturing and vaccine development preparations take place;
Risk-Sharing Fee	means any sum which is due from the Authority to the Supplier (if any) in the event of the cancellation or reduction of an Order, and is described in the relevant provision of this Agreement as a Risk-Sharing Fee;
Seed Virus	means a Pandemic primary seed virus provided to the Supplier from a World Health Organization reference laboratory or a World Health Organization essential regulatory laboratory;
Seed Virus Receipt	means the receipt of a Seed Virus by or on behalf of the Supplier which is capable of being used for commercial production of the Product;
Service Credit	shall have the meaning given in Schedule 6;
Slavery Act	shall have the meaning given in Clause 33.2.1;
SME	means an enterprise falling within the category of micro, small and medium-sized enterprises defined by the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises;
SME Management Information Reports	shall have the meaning referred to in Clause 32.5;
Social Value Commitments	has the meaning given in Clause 34.1;
Specific Criteria	means each event specified in column 3 of Schedule 13, provided that it is understood by the Parties that each event is to be considered independently of, and not cumulative to, any other events which may be specified for that particular

Words and Expressions	Meaning
	Pandemic phase;
Specification	means the specification set out in Schedule 2;
Staff	means all persons employed by the Supplier to perform its obligations under this Agreement together with the Supplier's servants, agents, suppliers and Sub-contractors used in the performance of its obligations under this Agreement;
Sub-contract	means a contract between two or more suppliers, at any stage of remoteness from the Supplier in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Agreement;
Sub-contractor	means a third party supplier who is a party to a Sub-contract;
Summary of Product Characteristics	means the summary of product characteristics approved by the Licensing Authority for the Marketing Authorisation as may be varied by the Variation of the Marketing Authorisation;
Supply Chain Transparency Information Template	means the reporting template of that name in Annex 1 to Schedule 16;
Term	means the term of this Agreement being the period of four years commencing on the Effective Date, as may be extended or reduced in accordance with Clause 15;
Third Party Body	has the meaning given to it in Clause 14.9;
Total Allocated Volume	means Redacted Under FOIA Section 43(2), Commercial Interests;
Transparency Information	has the meaning given in Clause 20.6;
Transparency Reports	has the meaning given in Schedule 16;

Words and Expressions	Meaning
UK	means the United Kingdom of Great Britain and Northern Ireland;
UK GDPR	means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (c.16);
UK Manufacture	means that, in respect of the Product: (i) the drug substance manufacture is carried out in the UK; (ii) the drug product manufacture is carried out in the UK; (iii) the fill and finish of the final Product is carried out in the UK; and (iv) associated stockpiles of components and consumables for the Product are all located in the UK. Details of the relevant locations of each activity are set out in Schedule 7;
UK Manufacturing Capability	means the capability to meet the Manufacturing Commitment using UK Manufacture;

Words and Expressions	Meaning
Use	means use in any activities carried out by or on behalf of the Authority or any Administering Entity or any Devolved Administration in relation to the Product following delivery to or collection by the Authority including storage and distribution of the Product and its administration and the carrying out of a vaccination programme as well as the supply, resale or donation of the Product to any Crown Dependency or United Kingdom embassy anywhere in the world (including without limitation to any or all of the Devolved Administrations) and "Used" shall have an equivalent meaning. For the avoidance of doubt, the Supplier shall cooperate with the Authority to facilitate resale and/or donations to third parties subject to, inter alia, prohibitive Licensing Authority and other regulations, labelling and language differences, or where there may be conflict with the Supplier's exclusive distribution obligations with local representatives in the receiving country(ies) (if any);
Value Added Tax or VAT	means value added tax as provided for in the Value Added Tax Act 1994 (c.23);
Variation of the Marketing Authorisation	means: (i) any variation to the Marketing Authorisation required to ensure Full UK Population Coverage; and (ii) the Pandemic variation of the Marketing Authorisation changing the influenza virus strain from the Pandemic preparedness vaccine to the Pandemic virus, the resulting vaccine being the Pandemic specific vaccine licensed for use in the relevant Pandemic, or such equivalent authorisation procedure as may be in force at the relevant time;
VCSE	means a non-governmental organisation that is value-driven and which principally reinvests its surpluses to further social, environmental or cultural objectives;

Words and Expressions	Meaning
Volume	means the quantity of Product specified in an Order;
WHO Classification System	means the global Pandemic phases used by WHO to communicate the global situation. The 4 Pandemic influenza phases (interpandemic, alert, Pandemic and transition), reflect the WHO's risk assessment of the global situation regarding each influenza virus with Pandemic potential infecting humans; and
World Health Organization or WHO	means the World Health Organization or any equivalent or successor organisation during the Term.

1.2. In this Agreement unless a provision otherwise expressly provides:

1.2.1. references to persons shall be deemed to include those of either sex and also firms or any other body (whether corporate or unincorporated), trust, state or agency of state (in each case, whether or not having separate legal personality);

1.2.2. words importing the singular number only shall include the plural number and vice versa;

1.2.3. references to any statute or order shall include any statutory extension, modification, amendment or re-enactment thereof and any order, regulation or bye-law made thereunder;

1.2.4. any reference to legislation shall, when interpreting this Agreement in relation to its applicability in Scotland, Northern Ireland and/or Wales in circumstances where there is equivalent legislation in Scotland, Northern Ireland and/or Wales, be interpreted pursuant to the country specific legislation;

1.2.5. a reference in this Agreement which immediately before Exit Day was a reference to (as it has effect from time to time):

1.2.5.1. any EU regulation, EU decision, EU tertiary legislation or provision of the EEA agreement ("**EU References**") which is to form part of domestic Law by application of section 3 of the European Union (Withdrawal) Act 2018 (c.16) shall be read as a reference to the EU References as they form part of domestic Law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (c.16) as modified by domestic Law from time to time; and

1.2.5.2. any EU institution or EU authority or other such EU body shall be read as a reference to the UK institution, authority or body to which its functions were transferred;

1.2.6. Schedules shall mean the schedules to this Agreement;

1.2.7. Clauses shall mean the clauses of this Agreement;

1.2.8. headings shall be deemed not to form part of this Agreement and accordingly shall not be taken into account in the construction or interpretation thereof;

1.2.9. all communication between the Parties relating to a notice or other communication required under this Agreement shall be in writing unless otherwise expressly specified in this Agreement. Where non-written notice is permissible under this Agreement, such notice shall be confirmed in writing by the Party giving such notice;

1.2.10. each and every obligation of a Party under this Agreement is to be performed at that Party's cost; and

1.2.11. references in this Agreement to a day or to the calculation of time frames are references to a calendar day unless expressly specified as a Business Day.

1.3. Where a term of this Agreement provides for a list of one or more items following the word "including" or "includes" then such list is not to be interpreted as being an exhaustive list. Any such list shall not be treated as excluding any item which might have been included in such list having regard to the context of the contractual term in question. The ejusdem generis principle is not to be applied when interpreting this Agreement. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.

1.4. All monetary amounts are expressed in pounds sterling but in the event that pounds sterling is replaced as legal tender in the United Kingdom by a different currency then all monetary amounts shall be converted into such other currency at the rate prevailing on the date such other currency first became legal tender in the United Kingdom.

1.5. Where the holder of the Marketing Authorisation is a third party, any obligation on the Supplier under this Agreement shall be taken as a requirement on the Supplier to procure the compliance of the holder of the Marketing Authorisation with such obligation to the extent necessary to ensure the relevant obligation is fully met.

1.6. Any reference to a Party "procuring" another person to act or omit to act in a certain manner shall mean that the Party so procuring shall be liable for any default on the part of the person acting or omitting to act in that manner.

1.7. All references to this Agreement include (subject to all relevant approvals) a reference to this Agreement as amended, supplemented, substituted, novated or assigned from time to time.

1.8. Any reference to “meet” or “meeting” (in the sense of getting together) shall be interpreted to mean through a face-to-face meeting or by videoconference, telephone conference or other suitable means.

1.9. In the event of any ambiguity or contradiction between the Conditions of Contract (being Clauses 1 to 42 of this Agreement) and the Schedules, the Conditions of Contract shall prevail. In the event of any ambiguity or contradiction between the Schedules they shall be given the following priority for the purposes of interpretation:

1.9.1. Schedule 2: Specification;

1.9.2. Schedule 5: Delivery Schedule;

1.9.3. Schedule 6: Key Performance Indicators;

1.9.4. Schedule 3: Contract Price;

1.9.5. Schedule 8: Contract Management;

1.9.6. Schedule 9: Supplier's Business Continuity Plan;

1.9.7. Schedule 10: Change Control Process;

1.9.8. Schedule 1: Preparatory Activities;

1.9.9. Schedule 7: Manufacturing Facilities;

1.9.10. Schedule 12: Delivery of Unlicensed Product;

1.9.11. Schedule 11: Provisions to apply on use of the Alternative Release Methodology;

1.9.12. Schedule 4: Conditions that apply should the Authority require the Supplier to switch to manufacture of the Product in advance of Declaration of a Pandemic; and

1.9.13. Schedule 13 to Schedule 19 (inclusive) in the order in which they appear.

1.10. The Parties accept and agree that in order to maintain consistency with the Offer, the Parties have incorporated certain responses included in the Offer into this Agreement and where the uncapitalised terms and language used in such responses do not reflect the defined terms set out in this Clause 1, such terms shall be given their ordinary meaning and shall be interpreted accordingly.

2. APPOINTMENT OF SUPPLIER

2.1. The Authority appoints the Supplier to:

2.1.1. undertake all activities necessary to be able to manufacture and supply the Product in a Pandemic;

2.1.2. ensure the capacity which is the subject of the Manufacturing Commitment is available for the benefit of the Authority in the event of a Pandemic;

2.1.3. upon the placing of an Order by the Authority, manufacture and supply the Product; and

2.1.4. fulfil all other Supplier obligations in this Agreement,

in accordance with the terms and conditions set out in this Agreement.

3. ACTIVITIES TO BE UNDERTAKEN PRIOR TO MANUFACTURE OF THE PRODUCTS

3.1. The Supplier shall throughout each Preparedness Phase:

3.1.1. undertake all necessary activities to ensure that the Supplier is able to manufacture the Total Allocated Volume and deliver the Total Allocated Volume in accordance with the Delivery Schedule in the event of a Pandemic, including:

3.1.1.1. the Preparatory Activities;

3.1.1.2. stockpiling relevant materials;

3.1.1.3. training Staff;

3.1.1.4. making arrangements for increased Staff sickness levels to be covered either by redeploying Staff or operating the Manufacturing Facilities with reduced staffing levels;

3.1.1.5. putting all relevant third party contracts in place; and

3.1.1.6. procuring the availability of all supplies that cannot be stockpiled;

3.1.2. ensure that the Alternative Release Methodology, if successfully developed and approved by the Licensing Authority, is:

3.1.2.1. available for use by the Supplier; or

3.1.2.2. available for internal decisions regarding formulation of the Product prior to Reagent availability;

3.1.3. grow emerging influenza virus strains to identify the upper and lower growth limits of such strains; and

3.1.4. monitor research and development in the field of influenza vaccines and relevant manufacturing technologies and share any material new information with the Authority. In the light of such information, the Supplier shall implement, where appropriate, all commercially reasonable and lawful measures to reduce the likelihood of injury to patients from the administration of the Product.

3.2. Immediately upon the escalation of the World Health Organization phases of alert in respect of an influenza Pandemic to Alert Stage B (Preparation Stage) under the Revised WHO Classification System, the Supplier shall:

3.2.1. undertake the Preparatory Pandemic Work insofar as it has not been undertaken in accordance with Clause 3.1;

3.2.2. commence dialogue with the Licensing Authority on the requirements for, and commence and undertake all necessary work in respect of its application for, a Variation of the Marketing Authorisation; and

3.2.3. throughout the phase until a Pandemic is declared, hold regular meetings with the Authority, at a minimum every two weeks, to discuss and share information relating to the epidemiological situation, accessibility of Seed Viruses to the Supplier, the current use of the Supplier's manufacturing facilities, relevant assessments of the Supplier's other customers under advance purchase agreements, public health and regulatory agencies

globally and other information relevant to the Authority's potential decision to place an Order in accordance with Clause 4.1.3.

3.3. Upon the earlier of (i) the Declaration of a Pandemic; and (ii) the Authority placing an Order under Clause 4.1.3, the Supplier shall:

3.3.1. continue with any activities set out in Clause 3.2 which have not yet been completed;

3.3.2. immediately commence the preparation of the Manufacturing Facilities for the manufacture of the Product, unless agreed otherwise in writing with the Authority;

3.3.3. submit its application for a Variation of the Marketing Authorisation at such time as it is able to provide data consistent with the requirements of the Licensing Authority and notify the Authority in writing of the decision of the Licensing Authority as soon as reasonably practicable following receipt of such decision; and

3.3.4. promptly obtain each relevant Pandemic primary Seed Virus and the Reagent following such Seed Virus or Reagent being made available by the World Health Organization or World Health Organization reference laboratory or World Health Organization essential regulatory laboratory as applicable.

3.4. The Supplier confirms and agrees that in the event of a Pandemic or upon escalation of the World Health Organization phases of alert in respect of an influenza Pandemic to Alert Stage C under the Revised WHO Classification System, the Supplier shall inform the Authority in writing of:

3.4.1. the anticipated date of Seed Virus Receipt by the Supplier and receipt of the Reagent within twenty four (24) hours of being informed of such date in respect of each of the Seed Virus and the Reagent by the World Health Organization or a World Health Organization reference laboratory or a World Health Organization essential regulatory laboratory as appropriate; and

3.4.2. Seed Virus Receipt and the receipt of the Reagent within twenty four (24) hours of each of Seed Virus Receipt and receipt of the Reagent. The Supplier shall further inform the Authority in writing immediately upon the Supplier becoming aware of any likely delays in such Seed Virus Receipt or receipt of the Reagent.

3.5. The Supplier shall commence growth of the Seed Virus immediately upon its receipt and provide to the Authority in writing the yield results of the Seed Virus and the results of the Reagent assay or Alternative Release Methodology as soon as each of them is available and shall promptly notify the Authority in writing should there be any change(s) to such results. The Supplier shall as reasonably required by the Authority discuss the results of the yield and the Reagent assay or Alternative Release Methodology with the Authority and promptly respond to all questions raised by the Authority. The Supplier shall, if requested by the Authority, attend a meeting with the Authority to discuss such results and the Supplier shall ensure that appropriately qualified Staff are available to attend such meeting within two (2) Business Days of being so requested.

3.6. The Parties acknowledge that the World Health Organization phases of alert and/or the classification system in respect of an influenza Pandemic may change during the Term. Should any such changes take place the Authority shall be entitled to make any changes to this Agreement which the Authority reasonably believes are necessary to reflect the impact of the changes to the classification system, provided that the Authority shall obtain the prior written consent of the Supplier to such changes, such consent not to be unreasonably withheld or delayed. The Supplier shall act promptly and reasonably in agreeing any changes with the Authority under this Clause 3.6 which are likely to have a material adverse commercial impact on the Supplier.

4. ORDER PROCESS

4.1. The Supplier confirms and agrees that:

4.1.1. there is no obligation on the Authority to place an Order during the Term or at any other time;

4.1.2. the Authority reserves the right to place an Order as provided in this Clause 4 in respect of each Pandemic occurring during the Term up to the Total Allocated Volume for each Pandemic; and

4.1.3. the Authority reserves the right to place an Order upon the escalation of the World Health Organization phases of alert in respect of an influenza Pandemic to Alert Stage B (Preparation Stage) under the Revised WHO Classification System, subject to the conditions set out in Schedule 4.

4.2. Subject to Clause 4.1.3, the Authority is not entitled to place an Order until the relevant Declaration of a Pandemic. Where the Authority elects to place an Order following the Declaration of a Pandemic, the Authority shall place such Order in respect to that Pandemic no later than the later of:

4.2.1. Redacted Under FOIA Section 43(2), Commercial Interests following the date of receipt by the Authority of written notice from the Supplier of Seed Virus Receipt; and

4.2.2. Redacted Under FOIA Section 43(2), Commercial Interests following the date of the Declaration of a Pandemic.

For the avoidance of doubt, save as otherwise provided in this Agreement, the Supplier shall not be obliged to accept any Order received after the relevant later date under this Clause 4.2. Without prejudice to the Authority's rights pursuant to other Clauses of this Agreement, the Authority shall be entitled to reduce, cancel or increase the Order (for the avoidance of doubt not to exceed the Total Allocated Volume) at its sole discretion until the relevant later date under this Clause 4.2.

4.3. The Volume ordered shall be at the sole discretion of the Authority provided always that: (i) the Volume ordered in relation to a specific Pandemic under this Clause 4 shall be no greater than the Total Allocated Volume; and (ii) the Volume of any Order shall be no less than the minimum purchase order volume of Redacted Under FOIA Section 43(2), Commercial Interests Doses of Product, or as may be set out in Schedule 4 where Schedule 4 is applicable.

4.4. For the avoidance of doubt, the Parties confirm and agree that the Total Allocated Volume is in respect of one Pandemic only and that the Total Allocated Volume

remains the same for subsequent Pandemics during the Term irrespective of the volume ordered in a specific Pandemic.

4.5. Should the Authority not place an Order as set out in Clause 4.2, the Authority shall be deemed not to require any Product in relation to the Pandemic at that time, and should the Authority place an Order for less than the Total Allocated Volume, and not adjust that Order as permitted under Clause 4.2, last paragraph, the Authority shall, subject to Clauses 4.9, 4.10, 5.3, 5.11 and 7.2.3, be deemed not to require any Product in addition to the number of Doses covered by the Order placed. In either of these cases, this shall not have any impact upon the Authority's right to place an Order in the event of a subsequent Pandemic during the Term. For the avoidance of doubt, should the Authority adjust an Order as permitted under Clause 4.2, last paragraph, then the Authority shall be deemed not to require any Product in addition to the number of Doses covered by such Order as adjusted on the earlier of: (i) the relevant later date under Clause 4.2; and (ii) the date on which the Authority confirms in writing that it is not going to reduce, cancel or increase the Order placed.

4.6. The Supplier shall provide to the Authority a Delivery Schedule setting out the dates and quantity for delivery of the Product (and such dates and quantity shall be calculated in accordance with the Schedule 5) on or before the later of:

4.6.1. Redacted Under FOIA Section 43(2), Commercial Interests or

4.6.2. Redacted Under FOIA Section 43(2), Commercial Interests; or

4.6.3. Redacted Under FOIA Section 43(2), Commercial Interests.

4.7. Where the Supplier will be obliged to provide the Delivery Schedule pursuant to Clause 4.6 and has not yet done so, the Supplier shall provide to the Authority within Redacted Under FOIA Section 43(2), Commercial Interests of the date of an Order an estimate of the dates and quantity for delivery of the Product based on the then available information on the likely Actual Yield (as defined in Schedule 5). Should such estimate of the dates and quantity for delivery of the Product change at any time before the Supplier provides the Delivery Schedule to the Authority, the Supplier shall provide to the Authority an updated estimate of the dates and quantity for delivery of the Product. For the avoidance of doubt, the Supplier acknowledges and agrees that provision of one or more estimated delivery schedules pursuant to this Clause 4.7 is without prejudice to the Supplier's obligations pursuant to Clause 4.6.1 or Clause 4.6.2.

4.8. In the event that escalation of the World Health Organization phases of alert in respect of an influenza Pandemic to Alert Stage C under the Revised WHO Classification System occurs during a Pandemic in respect of a different influenza virus strain and/or following an Order being placed under Clause 4.1.3 in respect of a different influenza virus strain, the Parties will discuss in good faith and agree if any changes are needed to be made to this Agreement to facilitate the most efficient supply of pandemic vaccine in respect of each virus strain.

4.9. If: (a) the World Health Organization reduces the phase of alert in respect of a particular influenza virus strain: (i) from Pandemic Phase to Alert Stage C or below under the Revised WHO Classification System, or (ii) from Alert Stage C to Alert Stage B (Preparation Stage) or below under the Revised WHO Classification System, and (b) the phase of alert is subsequently increased by the World Health

Organisation to Pandemic Phase under the WHO Classification System or Alert Stage C under the Revised WHO Classification System respectively in relation to the same influenza virus strain, it shall be deemed for the purpose of this Agreement to be a different influenza Pandemic. In such circumstances the Authority shall, following the subsequent increase in the phase of alert, be entitled to place an Order for up to the Total Allocated Volume in accordance with the provisions of this Agreement, irrespective of any volume of Product previously ordered in respect of the same influenza virus strain. In such event, the Supplier will use Commercially Reasonable Endeavours to accommodate such Order, and the price for the Product shall be as set out in Schedule 3 Redacted Under FOIA Section 43(2), Commercial Interests prior to the Authority placing an Order in accordance with this Clause 4.9. The Parties acknowledge that given the particular circumstances of placing Orders in a supply-constrained situation, Redacted Under FOIA Section 43(2), Commercial Interests by the Supplier to the Authority and only such Redacted Under FOIA Section 43(2), Commercial Interests. Without prejudice to the immediately preceding sentence, the terms of delivery (including the Delivery Schedule) of such Doses Redacted Under FOIA Section 43(2), Commercial Interests. As part of such Delivery Schedule the Supplier shall describe the circumstances upon which the Supplier has made the determination, reflecting its obligations to use such Commercially Reasonable Endeavours as described in this Clause 4.9, of the number of Doses that will be delivered for such new influenza Pandemic, together with information on the then current status of its supply chain.

4.10. If the World Health Organization or Licensing Authority: (a) declares that the influenza virus strain causing the Alert Stage C or Pandemic Phase under the Revised WHO Classification System has mutated or undergone a reassortment to such an extent that the Product will not be or is no longer effective; and (b) the phase of alert in respect of the relevant influenza virus strain remains Alert Stage C or Pandemic Phase under the Revised WHO Classification System, the mutated virus or virus that has undergone a reassortment shall be deemed for the purposes of this Agreement to be the subject of a different influenza Pandemic. In such circumstances the Authority shall, following the declaration of mutation or reassortment, be entitled to place an Order for up to the Total Allocated Volume in accordance with the provisions of this Agreement, irrespective of any volume of Product previously ordered in respect of the influenza virus strain prior to such mutation or reassortment. In such event, the Supplier will use Commercially Reasonable Endeavours to accommodate such Order, and the price for the Product shall be as set out in Schedule 3 Redacted Under FOIA Section 43(2), Commercial Interests prior to the Authority placing an Order in accordance with this Clause 4.10. The Parties acknowledge that given the particular circumstances of placing Orders in a supply-constrained situation, Redacted Under FOIA Section 43(2), Commercial Interests by the Supplier to the Authority and only such Redacted Under FOIA Section 43(2), Commercial Interests. Without prejudice to the immediately preceding sentence, the terms of delivery (including the Delivery Schedule) of such Doses Redacted Under FOIA Section 43(2), Commercial Interests. As part of such Delivery Schedule the Supplier shall describe the circumstances upon which the Supplier has made the determination, reflecting its obligations to use such Commercially Reasonable Endeavours as described in this Clause 4.10, of the number of Doses that will be delivered under such additional Order for such different influenza Pandemic, together with information Redacted Under FOIA Section 43(2), Commercial Interests and all other Supplier obligations that arise following the Declaration of a Pandemic and/or the placing of an Order shall apply in respect of the influenza virus strain that has mutated or undergone a reassortment.

5. CANCELLATION OF OR REDUCTION OR INCREASE OF THE VOLUME IN AN ORDER

5.1. In the event that:

5.1.1. the Supplier does not commence dialogue with the Licensing Authority on the submission of quality and manufacturing data together with non-clinical trial data in accordance with the guidance issued by the Licensing Authority on the requirements for a Variation of the Marketing Authorisation within two (2) months of Seed Virus Receipt and/or the Supplier does not use its best endeavours to submit an application for Variation of the Marketing Authorisation as soon as possible following the commencement of such dialogue; or

5.1.2. the Licensing Authority refuses to grant a Variation of the Marketing Authorisation; or

5.1.3. the Licensing Authority does not grant a Variation of the Marketing Authorisation within three (3) months of the submission by the Supplier of quality and manufacturing data together with non-clinical trial data, Redacted Under FOIA Section 43(2), Commercial Interests

5.2. Should the Authority reduce the Volume, cancel an Order or terminate this Agreement pursuant to Clause 5.1, then the Authority shall be entitled to damages for breach of contract Redacted Under FOIA Section 43(2), Commercial Interests.

5.3. Should the Authority reduce the Volume or cancel an Order pursuant to Clause 5.1, and the Variation of the Marketing Authorisation is subsequently granted, the Authority shall be entitled to place an Order for up to the Total Allocated Volume, provided such Order is placed within five (5) calendar days of receipt by the Authority of written notice from the Supplier under Clause 3.3.3 that such a Variation of the Marketing Authorisation has been granted. In such event, the Supplier will use Commercially Reasonable Endeavours to accommodate such Order, and the price for the Product shall be as set out in Schedule 3 Redacted Under FOIA Section 43(2), Commercial Interests prior to the Authority placing an Order in accordance with this Clause 5.3. The Parties acknowledge that given the particular circumstances of placing Orders in a supply-constrained situation, Redacted Under FOIA Section 43(2), Commercial Interests by the Supplier to the Authority and only such Redacted Under FOIA Section 43(2), Commercial Interests. Without prejudice to the immediately preceding sentence, the terms of delivery (including the Delivery Schedule) of such Doses Redacted Under FOIA Section 43(2), Commercial Interests. As part of such Delivery Schedule the Supplier shall describe the circumstances upon which the Supplier has made the determination, reflecting its obligations to use such Commercially Reasonable Endeavours as described in this Clause 5.3, of the number of Doses that will be delivered as part of such Order, together with information Redacted Under FOIA Section 43(2), Commercial Interests.

5.4. Following the placing of an Order, the Authority and the Supplier shall hold a meeting every week (or more frequently as requested by the Authority) until the Volume has been delivered to the Authority to enable the Authority to review the Volume that remains to be supplied to the Authority. The Supplier shall ensure that authorised senior representatives of the Supplier attend such meetings and the Supplier shall provide to the Authority any information that it reasonably requires.

5.5. The Authority shall be entitled to cancel an Order or the remaining Volume under an Order as appropriate by serving written notice on the Supplier:

5.5.1. if during Use of the Product there is an adverse reaction to the Product other than one described in the Summary of Product Characteristics and, as a result: (i), the Licensing Authority and/or the Joint Committee on Vaccination and Immunisation or a successor body thereto advises the Authority that it should cease using the Product altogether; or (ii) the Licensing Authority withdraws the Marketing Authorisation. In the event of such cancellation, the Authority shall pay a Risk-Sharing Fee to the Supplier equivalent to Redacted Under FOIA Section 43(2), Commercial Interests of the total price due for the cancelled Doses under such Order. The obligation to pay Redacted Under FOIA Section 43(2), Commercial Interests under Clause 5.6.3 shall not apply to any Doses in respect of which the Volume is cancelled under this Clause 5.5.1; or

5.5.2. if the World Health Organization, or equivalent body, reports that the Pandemic is over or that there are no reported new cases of influenza or influenza like illness across Europe relating to the Pandemic, as demonstrated by the internationally agreed qualitative and quantitative indicators reported over a six (6) week period by Member States to the World Health Organization in accordance with its global surveillance reporting Guidance issued to Member States during the Pandemic; or

5.5.3. in accordance with Clause 22, to the extent the Supplier serves notice under Clause 22.6 and with regard to the number of Doses that such claim for relief relates to; or

5.5.4. if the Authority becomes entitled to terminate this Agreement for whatever reason.

5.6. Following termination of the Agreement or cancellation of an Order or cancellation of some or all of the remaining Volume under this Agreement, the Authority shall be under no obligation to pay the Supplier other than for:

5.6.1. any Product delivered under this Agreement prior to the termination of the Agreement or cancellation of such Order or Volume;

5.6.2. any Doses in respect of which the Authority has not cancelled the Volume and which are subsequently delivered under this Agreement;

5.6.3. all undelivered Doses scheduled for delivery to the Authority within Redacted Under FOIA Section 43(2), Commercial Interests after the date of notice of the relevant termination or cancellation where:

5.6.3.1. termination or cancellation is pursuant to Clauses 5.5.2, 5.7.1, 5.7.3, 5.7.4, 5.7.5, 5.7.6, or Schedule 4 Paragraph 6.2; or

5.6.3.2. termination or cancellation is pursuant to Clauses 5.5.1, 5.7.2 or 5.7.5 and the exception or limitation to such payment set out in the applicable Clause does not apply; and

5.6.4. any Risk-Sharing Fee which falls due in accordance with this Agreement, being any applicable Risk-Sharing Fee set out in Clauses 5.5.1, 5.7.1, 5.7.2,

5.7.3, 5.7.4, 5.7.5, 5.7.6 and/or Schedule 4 Paragraph 6.2.

5.7. The Authority shall further be entitled to reduce the Volume by serving written notice on the Supplier if:

5.7.1. Redacted Under FOIA Section 43(2), Commercial Interests; or

5.7.2. either:

(A) during Use of the Product there is an adverse reaction to the Product other than as described in the Summary of Product Characteristics and, as a result, the Licensing Authority or a successor body thereto: (i) advises the Authority that it should cease using the Product in respect of certain categories of the population; or (ii) amends or varies the Marketing Authorisation; or

(B) the Licensing Authority or a successor body thereto for reasons other than under (A) amends or varies the Marketing Authorisation,

so that the Product must not be used in respect of certain categories of the population.

Any such reduction in the Volume shall be proportionate to the categories of population not to be so vaccinated and shall apply in respect only to those Doses not yet delivered. The obligation Redacted Under FOIA Section 43(2), Commercial Interests under Clause 5.6.3 shall not apply to any Doses in respect of which the Volume is cancelled under this Clause 5.7.2. In the event of such reduction set forth in this Clause 5.7.2, Redacted Under FOIA Section 43(2), Commercial Interests due for the cancelled Doses under such Order; or

5.7.3. the Licensing Authority or a successor body thereto:

5.7.3.1. advises the Authority that the Supplier's data supports the efficacy of a reduced number of Doses of the Product per patient in place of the number of Doses per patient recommended at the time of the Order; or

5.7.3.2. amends or varies the Marketing Authorisation so that a reduced number of Doses of the Product per patient is allowed in place of the number of Doses per patient recommended at the time of the Order.

Any such reduction in the Volume shall be no greater than the number of Doses rendered unnecessary due to the implementation of the new dosage regime or amended or varied Marketing Authorisation going forward. In the event of such reduction set forth in this Clause 5.7.3, Redacted Under FOIA Section 43(2), Commercial Interests of the total price due for the cancelled Doses under such Order; or

5.7.4. Redacted Under FOIA Section 43(2), Commercial Interests

5.7.4.1. inaccurate, such that fewer Doses than such number of Doses that would result from the Yield Assumption can now be delivered within the relevant timelines of a Delivery Schedule that results from the Yield Assumption (an "**Inaccuracy**"); or

5.7.4.2. subsequently changed, which results in an Inaccuracy, but such change was not notified to the Authority in writing.

Any such reduction in the Volume shall be at the discretion of the Authority but in no event will the reduction exceed the quantity of Doses due to be delivered that would not be delivered within the relevant timelines as a consequence of the Inaccuracy. In the event of such reduction Redacted Under FOIA Section 43(2), Commercial Interests for the cancelled Doses under such Order; or

5.7.5. Redacted Under FOIA Section 43(2), Commercial Interests

5.7.6. Redacted Under FOIA Section 43(2), Commercial Interests

5.7.7. the circumstances described in Clause 11.4 apply.

5.8. Any reduction in the Volume pursuant to this Clause 5 shall be Redacted Under FOIA Section 43(2), Commercial Interests unless otherwise agreed in writing between the Parties.

5.9. Following service of notice to amend the Volume by the Authority pursuant to Clause 5.1 or Clause 5.7, the Volume shall be deemed to have been amended accordingly. The Supplier shall manufacture and supply the Volume so amended and the Authority shall pay for the Volume so amended.

5.10. [Not Used.]

5.11. Should, in cases other than as set forth in Clause 4.9, 4.10, 5.3 or 7.2.3, during a Pandemic the Authority request that the Supplier supplies additional Doses of the Product in excess of the Volume (which may, for the avoidance of doubt and notwithstanding the provisions of Clause 4, be in excess of the Total Allocated Volume), then the Supplier will use Commercially Reasonable Endeavours to accommodate such Order, Redacted Under FOIA Section 43(2), Commercial Interests. The Parties acknowledge that given the particular circumstances of placing Orders in a supply-constrained situation, the actual increase might deviate from the expected increase communicated by the Supplier to the Authority and only such actual increase compared to the Original Purchase Price concerned will be invoiced to the Authority. Without prejudice to the immediately preceding sentence, the terms of delivery (including the Delivery Schedule) of such Doses are to be the subject of a separate agreement at the time. As part of such Delivery Schedule the Supplier shall describe the circumstances upon which the Supplier has made the determination, reflecting its obligations to use such Commercially Reasonable Endeavours as described in this Clause 5.11, of the number of Doses that will be delivered as per the Authority's request, together with information on the then current status of its supply chain.

6. MANUFACTURE AND SUPPLY

6.1. Should the Authority place an Order, the Supplier shall supply the Volume to the

Authority in accordance with this Agreement. The Authority shall purchase the Volume and pay the Contract Price in accordance with Clause 14.

6.2. If the Supplier uses the Alternative Release Methodology then the provisions of Schedule 11 shall apply.

6.3. The Supplier shall ensure that all Doses of the Product supplied to the Authority under this Agreement:

6.3.1. comply fully with the Specification and the Marketing Authorisation;

6.3.2. are supplied in accordance with the Delivery Schedule, provided that in the case that the World Health Organization, or equivalent body, reports that the Pandemic is over or that there are no reported new cases of influenza or influenza like illness across Europe relating to the Pandemic, as demonstrated by the internationally agreed qualitative and quantitative indicators reported over a six (6) week period by member states to the World Health Organization ("**Member States**") in accordance with its global surveillance reporting Guidance issued to Member States during the Pandemic, the Supplier shall, upon providing notice to the Authority, be released from delivering any Doses for which bulk manufacturing has not yet commenced upon the date of such reporting by the World Health Organization or equivalent body as mentioned above in this sub-Clause 6.3.2;

6.3.3. have the shelf life set out in Schedule 2 less any period relating to the release of the Product, provided that such release period shall not reduce the shelf life of the Product Redacted Under FOIA Section 43(2), Commercial Interests; and

6.3.4. have not been rejected by any other entity on grounds of quality or been outside the Supplier's control prior to their supply to the Authority.

6.4. The Supplier shall:

6.4.1. ensure that it has and maintains at all times during the Term, manufacturing capacity sufficient to comply with its obligations under this Agreement, including Clause 6.1 and Clause 7.1;

6.4.2. keep the Manufacturing Facilities in a state and condition necessary to enable the Supplier to comply with its obligations to supply the Product to the Authority in accordance with this Agreement; and

6.4.3. permit or procure permission for the Authority or Authority's nominee during normal business hours having given reasonable advance notice access to the Manufacturing Facilities to enable the Authority to inspect and review the production and quality assurance processes in relation to the Product.

6.5. The Supplier confirms and agrees that it will not have the exclusive right to supply Pandemic influenza vaccine to the Authority and that the Authority may at any time order and purchase Pandemic influenza vaccine and/or the Product from any third party or entity whether identified as a supplier of Pandemic influenza vaccine at the Effective Date or not.

6.6. The Authority reserves the right to appoint an Authorised Agent to act on its behalf

in dealing with the Supplier and/or in supplying the Product to Administering Entities, Devolved Administrations or patients. For the avoidance of doubt, such appointment shall be without prejudice to the Supplier's delivery obligation being limited to such locations under such circumstances as set out in Clause 7.4.4. Where the Authority so appoints an Authorised Agent to act on its behalf in dealing with the Supplier, the Authority shall notify the Supplier in writing of this appointment and the Supplier shall continue to be bound by its obligations under this Agreement and shall deal with and take instructions from such Authorised Agent. For the avoidance of doubt, there will be no obligation on the Authority to notify the Supplier where the Authority has appointed an Authorised Agent to act on its behalf in supplying the Product to Administering Entities, Devolved Administrations or patients.

6.7. Throughout the manufacture of the Product, the Supplier shall undertake trials and tests of the Product and gather evidence in relation to the Product's efficacy. Immediately upon receipt of the results of such test and trials the Supplier shall assess the results in relation to the dosage requirements for adequate vaccination. The Supplier shall forthwith inform the Authority in writing of the outcome of such assessments and the results of the test and trials and share data with the Authority regarding the results.

6.8. In the event that Products are delivered before their delivery date as calculated in accordance with Schedule 5, then the Authority shall be entitled in its sole discretion to refuse to take delivery of such Products until the contractual date for delivery. Should the Authority have exercised any of its rights pursuant to Clauses 5.1, 5.5 and 5.7, the Supplier acknowledges that the Authority shall be under no obligation to take delivery of such Products other than as stated in the Authority's notice served on the Supplier pursuant to Clauses 5.1, 5.5 and 5.7 or as otherwise agreed.

6.9. Where the Product is unlicensed at the time of delivery to or collection by the Authority, and the Variation of Marketing Authorisation is subsequently granted, the Supplier shall provide the Authority with the patient information leaflets for the Product and any other relevant information from the Licensing Authority concerning the use or safety of the Product within fourteen (14) days of the grant of such Variation of Marketing Authorisation.

6.10. Should the Product be unlicensed at the time that the Product is ready for delivery to the Authority, the provisions of Schedule 12 will apply until the grant of the Variation of the Marketing Authorisation in respect of the relevant Product.

6.11. Should during the Term the Licensing Authority grant to the Supplier a different marketing authorisation from the Marketing Authorisation (in respect of an egg-based Pandemic influenza vaccine or the Supplier's then current Pandemic influenza vaccine), which the Supplier is capable of manufacturing at the Manufacturing Facilities ("**New Marketing Authorisation**"), the Supplier shall inform the Authority in writing of such grant of a New Marketing Authorisation within twenty-four (24) hours of it being so granted. The Authority shall be entitled on written notice to the Supplier to substitute such New Marketing Authorisation in place of the Marketing Authorisation for the purposes of interpretation of this Agreement. If the Supplier is not the holder of the New Marketing Authorisation but the Supplier is authorised by such holder to manufacture and supply vaccine licensed pursuant to this New Marketing Authorisation, then the provisions of this Clause 6.11 shall apply as if the Supplier was the holder of the New Marketing Authorisation.

6.12. Unless otherwise agreed by the Authority in writing, the Supplier will UK

Manufacture all Products supplied under this Agreement. To achieve this, the Supplier shall put in place the UK Manufacturing Capability within thirty (30) months of the Effective Date, and shall maintain the UK Manufacturing Capability for the remainder of the Term of this Agreement. As part of putting in place and maintaining such UK Manufacturing Capability, the Supplier will engage in any risk assessment carried out by the Centre for Protection of National Infrastructure (including by providing all requested help and access to personnel and premises to facilitate such risk assessment and by also implementing any risk mitigation measures it is recommended to adopt as part of such risk assessment). Without prejudice to any other right or remedy that the Authority may have, the Parties agree and accept that specific performance is an appropriate remedy in respect of any breach by the Supplier its obligations under this Agreement relating to UK Manufacture.

6.13. The Supplier is required to formally notify the Authority of its progress in achieving the UK Manufacturing Capability at six (6) monthly intervals from the Effective Date through the provision of interim reports (which include details of the Supplier's current progress and forecast time to complete). Where it is clear after twenty-four (24) months from the Effective Date that the Supplier will not meet the thirty (30) month timescale under Clause 6.12, the Supplier will notify the Authority in writing with the reasons together with its mitigation plan aimed at putting things back on track to meet such timescale.

6.14. The Supplier shall promptly provide a formal final written notification to the Authority once the UK Manufacturing Capability is in place, and shall provide written confirmation to the Authority annually thereafter that the UK Manufacturing Capability remains in place.

6.15. The Authority may audit the Supplier's compliance with Clause 6.12 at any time throughout the Term of this Agreement including by requesting additional information to verify such compliance, which the Supplier shall promptly provide following any such request from the Authority.

6.16. If the Supplier fails to deliver the UK Manufacturing Capability within thirty (30) months of the Effective Date, the Authority may (but shall not be required to):

6.16.1. terminate this Agreement in accordance with Clause 15.4.7;

6.16.2. in exceptional circumstances, extend the timeframe for the Supplier to put in place the UK Manufacturing Capability, such extension to be for up to a maximum of six (6) additional months; and/or

6.16.3. agree temporary alternative arrangements with the Supplier in relation to manufacture of the Product for up to a maximum of six (6) months. For the avoidance of doubt, the Supplier will be liable for all costs relating to the set-up and provision of such temporary alternative arrangements.

6.17. The Supplier will comply with its obligations under Schedule 14 (Diversification).

6.18. If the Authority transfers the Products outside of the United Kingdom, the Authority shall take full responsibility for the safe transportation of the relevant Doses of Product so transferred, and for the safe storage and distribution of such Doses, and shall indemnify the Supplier in full against any claims relating to the Product to the extent only that such claims result directly from the Authority's failure to ensure the safe onward transportation, or the safe storage or distribution, of Doses to any Crown

Dependency or United Kingdom embassy, or any other country, anywhere in the world. For the purposes of this Clause 6.18, "**safe**" shall mean in accordance with any cold-chain and other transportation, storage or distribution requirements applicable to the Products under Good Distribution Practice or European Public Assessment Report and with such additional reasonable requirements that may be notified to the Authority by the Supplier prior to such transportation, storage or distribution, as applicable, taking place. For the avoidance of doubt, the Supplier shall retain full responsibility for the safety, quality and efficacy of the Products transferred outside of the United Kingdom subject only to the Authority's transportation, storage and distribution related obligations set out in this Clause 6.18 and the indemnity by the Authority provided in Clause 6.18.1 and 6.18.2 below.

6.18.1. The Authority shall indemnify the Supplier in full against any and all loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Supplier or its affiliates arising from the Use of the Product supplied under this Agreement, or from any activity with such Product carried out, including administration, by any entity or person, in each case in a country or other territory where there is no valid marketing authorisation for the Product.

6.18.2. For claims relating to death or personal injury arising or resulting from the Use of the Product, or from any activity with the Product carried out, including administration, by any entity or person, in a country or other territory where there is a valid marketing authorisation for the Product, the indemnification provisions set out in Clause 18 shall apply.

7. DELIVERY AND DELAY

7.1. The Supplier confirms and agrees that it shall be obliged to deliver the Product in accordance with the Delivery Schedule.

7.2. For business contingency purposes and without prejudice to the Authority's other rights and remedies under this this Agreement:

7.2.1. where there is a risk of a delay or shortfall relating to the manufacture of the Product at a UK facility of the Supplier, the Supplier shall promptly notify the Authority of the same and shall use reasonable endeavours to mitigate any delay in such delivery or potential shortfall through the use of non-UK based facilities subject to the prior written approval of the Authority;

7.2.2. where the Supplier is unable to mitigate any delay in such delivery or shortfall in accordance with Clause 7.2.1, the Supplier shall promptly notify the Authority of the same and the Authority may upon written notice cancel such part of the impacted Order which will not be delivered during the first Redacted Under FOIA Section 43(2), Commercial Interests following the first delivery of Doses to the Authority, and place an alternative order for a product equivalent to the impacted Product from an alternative supplier; and

7.2.3. where similar circumstances as referred to in Clause 7.2.2 apply in a contract that the Authority may have with any third party supplier, the Authority may Redacted Under FOIA Section 43(2), Commercial Interests

7.3. Notwithstanding the provisions of Clause 7.1 and 7.2 and without prejudice to such provisions, should the Supplier anticipate that the delivery of the Product by the

Supplier will be delayed beyond the dates for delivery in the Delivery Schedule or that there will be a shortfall in the volume of Product delivered on these dates as measured against the Delivery Schedule:

7.3.1. the Supplier shall inform the Authority in writing immediately of any anticipated delays in delivery or shortfall in volume; and

7.3.2. the Supplier shall use its Commercially Reasonable Endeavours to remedy any delays in delivery or shortfall in volume so delivered forthwith to ensure that any delays in delivery or shortfall in volume do not impact on subsequent deliveries.

7.4. The Supplier shall:

7.4.1. subject to Clauses 7.2 and 7.3, deliver Doses of Product to the Authority consistent with the Delivery Schedule;

7.4.2. ensure that in each calendar month following the Authority placing an Order with the Supplier until such time as the relevant Order has been fulfilled or cancelled, the number of Doses of Product delivered to the Authority as a percentage of the total number of Doses of Product manufactured and shipped by the Supplier to all its customers shall be equal to or greater than the percentage of the Supplier's capacity reserved under Clause 13.6.5;

7.4.3. store all Doses of the Product when manufactured in a good and proper manner and in accordance with any relevant requirements in the Summary of Product Characteristics;

7.4.4. (A) deliver all Doses of the Product to the Authority's storage provider or distribution agent or Authorised Agent, as notified by the Authority, from time to time to a single location in any part of the United Kingdom other than Northern Ireland as specified in the Order, or to the Supplier's loading deck at the relevant Manufacturing Facility if the Authority notifies the Supplier that part or all of the Volume is to be collected by or on behalf of the Authority as detailed in Clause 7.10; or

(B) if there is no mechanism available to the Authority under applicable Law, including, for the avoidance of doubt, through NIMAR, to deliver the Product from the single location in Great Britain as described in Clause 7.4.4(A) to Northern Ireland, then, upon notice in writing by the Authority as part of the Order, the Supplier shall deliver such a number of Doses specified in the Order (which it should have otherwise delivered to Great Britain under Clause 7.4.4(A)) to the Authority's storage provider, distribution agent or Authorised Agent in Northern Ireland, under the conditions that:

7.4.4.1. the number of Doses indicated in such Order equals one or more full Batches and such Batches to Northern Ireland shall be delivered consecutively, either as the first or the last set of Batches of the overall Delivery Schedule, as identified in the Order; and

7.4.4.2. the Parties agree to adjust any Delivery Schedule, KPI and other performance requirements to take into account any consequences of the revised supply arrangement.

Notwithstanding what is stated under this Clause 7.4.4(B), the Authority shall use its Commercially Reasonable Endeavours to obtain approval for supply of the Product from Great Britain to Northern Ireland under NIMAR and should the Authority be granted such approval, this Clause 7.4.4(B) shall not apply. The parties acknowledge and agree that the detailed mechanism applying to delivery of Doses to Northern Ireland pursuant to this Clause 7.4.4(B) may be subject to change by agreement in writing between the Parties to reflect any changes in the applicable Law in relation to Northern Ireland.

7.4.5. be deemed to have delivered Doses of the Product to the Authority upon either:

7.4.5.1. delivery of the same to the Authority's storage provider or distribution agent or Authorised Agent, as notified by the Authority, at the relevant location, provided that the Supplier waits at the place of delivery: (i) for the Product to be unloaded by such storage provider or distribution agent or Authorised Agent at the relevant location; and (ii) until all relevant paperwork has been provided to such storage provider or distribution agent or Authorised Agent at the relevant location; or

7.4.5.2. collection of the same by or on behalf of the Authority, provided that all relevant paperwork has been provided to the Authority or entity collecting the Product; and

7.4.6. with the exception of where the Authority notifies the Supplier that it has decided to collect the Product, transport and deliver the Product in such manner necessary to ensure that it is delivered in good and usable condition and in accordance with any relevant requirements in the Summary of Product Characteristics.

7.5. The Supplier shall deliver all Doses of the Product securely packaged with the following details being shown clearly on the shipping carton or other such outer packaging:

7.5.1. a description of the Product using the Supplier's brand name and/or generic drug name;

7.5.2. the quantity in the package;

7.5.3. special directions for storage (if any);

7.5.4. expiry date for the Product in the package;

7.5.5. Batch number;

7.5.6. name of Supplier; and

7.5.7. any other information required by the Licensing Authority to be provided.

7.6. Subject to Clause 7.9, the Supplier shall be responsible for all transport and all related costs associated with the delivery of the Product. The Supplier shall be responsible for ensuring that the Product is delivered to the loading bay of the Authority's storage

providers or distribution agents or Authorised Agents and will cooperate in the unloading of the Product with such third parties as may be appropriate.

7.7. All third party carriers (other than the Authority's storage providers or distribution agents or Authorised Agents referred to in Clause 7.4) engaged to deliver the Product shall at no time be an agent of the Authority and accordingly the Supplier shall be liable to the Authority for the acts and omissions of all third party carriers engaged to deliver the Product to the Authority.

7.8. Should either Party have bona fide concerns regarding the security of transportation of the Product, such Party will forthwith raise by written notice such concerns with the other Party. The Parties will discuss and use their best endeavours to agree the most appropriate mode of transport and delivery of the Product and review such decision at appropriate intervals during the supply of the Product. The Parties acknowledge and agree that mode of transport and delivery may need to vary throughout the supply of the Product to reflect the circumstances at that time.

7.9. The Authority shall also have the right at its cost and expense to make specific security arrangements in respect of transport and delivery of the Product and to vary the mode of transport and delivery of the Product. The Supplier shall cooperate fully with the Authority and any sub-contractor of the Authority should the Authority exercise its rights under this Clause 7.9.

7.10. The Authority shall have the right to elect to collect the Product from the Manufacturing Facility. The Authority shall inform the Supplier should the Authority wish to exercise this right and the Parties shall agree the date(s) of such collection. The Supplier shall ensure that the Products are labelled in such a way that they are readily identified as Product ordered by and manufactured for the Authority. In the event the Authority exercises its right pursuant to this Clause 7.10, the Authority shall utilise equipment and storage facilities to be agreed with the Supplier to ensure compatibility with the temperature management and monitoring technologies employed by the Supplier and consistency with those steps that would otherwise be required to be employed by the Supplier to ensure cold chain compliance in the performance of this Agreement. The Supplier shall credit to the Authority any savings made by the Supplier as a result of the Authority so collecting the Product.

7.11. Subject to Clause 8.6:

7.11.1. risk in all Doses of the Product shall pass to the Authority upon completion of delivery to or collection by the Authority, its storage provider, or distribution agent, or Authorised Agent, as the case may be, of the relevant Doses so delivered or collected; and

7.11.2. title to all Doses of the Product shall pass to the Authority upon the delivery to, or collection by, the Authority, its storage provider, or distribution agent, as the case may be.

7.12. The Supplier shall supply the Product on pallets, unless otherwise instructed by the Authority. The Authority shall be under no obligation to return such pallets to the Supplier.

7.13. Each delivery of the Product shall be accompanied by an advice note providing the information set out in Clause 7.5 in respect of the whole delivery, together with:

7.13.1. the weight of the Product delivered;

7.13.2. unit of measure of the Product; and

7.13.3. the relevant Order number.

All ancillary paperwork and literature (including invoices) shall include the same information.

7.14. The labelling and marking of all packages of the Product and all relevant information accompanying them shall be in English.

7.15. The Supplier shall discuss and, other than to the extent required by the Licensing Authority, agree with the Authority in advance any changes to be made to labelling, instructions and/or patient information relating to the Product.

7.16. The Supplier shall promptly provide to the Authority following each delivery of Product, complete and accurate temperature records for each delivery of the Product to the Authority during the period of transport of the Product from the Manufacturing Facilities to the delivery location.

7.17. Where the Authority has ordered Product in accordance with the terms of this Agreement but the Supplier, having successfully manufactured such Product, does not supply some or all of the Product to the Authority and instead, and contrary to the terms of an Order and of this Agreement, supplies such Product to a third party, without the prior written consent of the Authority, then the Supplier shall pay to the Authority:

7.17.1. any excess in price between the fee the Authority would have paid for the supply of the relevant Doses had the Authority received such Product and the actual price paid by the third party so receiving such Product; and

7.17.2. any additional loss or damage which has not been compensated under Clause 7.17.1 and which the Authority has suffered arising from the Supplier supplying such Product to a third party.

8. INSPECTION AND REJECTION OF THE PRODUCTS

8.1. Subject to reasonable written notice, the Supplier shall permit any person authorised by the Authority to inspect work being undertaken in relation to the Products and/or the storage facilities used in the storage of the Products at all reasonable times at the Supplier's premises or at the premises of any Sub-contractor or agent of the Supplier in order to confirm that the Products are being manufactured and/or stored in accordance with Good Industry Practice and Good Manufacturing Practice and in compliance with the requirements of this Agreement and/or that stock holding and quality assurance processes are in accordance with the requirements of this Agreement.

8.2. The Authority shall carry out a visual inspection of the Product promptly and in any event within Redacted Under FOIA Section 43(2), Commercial Interests of the date of delivery to the Authority in accordance with Clause 7.4.4. Should the Authority elect to collect the Product in accordance with Clause 7.10, such visual inspection shall be carried out at the time of collection. Such visual inspection shall cover checking the relevant Batches of Product, to ensure there is no obvious damage, without the requirement of unpacking any pallet, checking Batch numbers and

expiry dates in accordance with delivery documents, checking the temperature logged by the monitoring devices included in the transport boxes, and quantity. The Authority shall notify the Supplier of any issues arising from such inspection promptly and in any event Redacted Under FOIA Section 43(2), Commercial Interests of the date of delivery to the Authority in accordance with Clause 7.4.4 or the date of collection, in accordance with Clause 7.10, or the Product delivered shall be deemed to have been accepted.

8.3. The Authority may reject any Doses of the Product:

8.3.1. where such visual inspection reveals such Doses or their packaging to be damaged and/or to have Batch numbers and/or expiry dates which do not correspond to the relevant delivery documents and/or the provisions of this Agreement (as determined during inspection under Clause 8.2); or

8.3.2. in respect of which the Supplier fails to provide complete and accurate temperature records in accordance with Clause 7.16 on the date of delivery; or

8.3.3. where the temperature of the Product during the period of transport falls outside the range of temperatures for the Product as detailed in the Specification provided that, following a prompt impact assessment, the Supplier is unable to demonstrate to the satisfaction of the Authority promptly and in any event within Redacted Under FOIA Section 43(2), Commercial Interests of the date of notice by the Authority of such temperature deviation, that notwithstanding the deviation in temperature the Product fully meets the requirements of the Specification. Where the temperature falls outside the range as set out in this Clause 8.3.3, during the period prior to any such demonstration by the Supplier, the relevant Product shall be stored in quarantine by the Authority and shall be deemed not to be delivered for the purposes of this Agreement until such demonstration by the Supplier.

8.4. Without prejudice to the provisions of Clause 8.7, upon the rejection of any Products in accordance with Clauses 8.3 and/or 8.9, the Supplier shall at the Authority's written request:

8.4.1. collect the Rejected Products at the Supplier's risk and expense promptly and in any event within Redacted Under FOIA Section 43(2), Commercial Interests of issue of written notice from the Authority rejecting the Products; and

8.4.2. without extra charge, promptly (and in any event within Redacted Under FOIA Section 43(2), Commercial Interests or such other time agreed by the Parties in writing acting reasonably) supply replacements for the Rejected Products to the Authority, subject to the Authority not cancelling its purchase obligations in accordance with Clause 8.7.

8.5. If the Supplier requests and the Authority accepts that the Rejected Products should be disposed of by the Authority rather than returned to the Supplier, the Authority reserves the right to charge the Supplier for the costs associated with the disposal of the Rejected Products and the Supplier shall promptly pay any such costs.

8.6. Risk and title in respect of any Rejected Products shall pass to the Supplier on the earlier of: (a) collection by the Supplier in accordance with Clause 8.4; or (b)

immediately following the expiry of Redacted Under FOIA Section 43(2), Commercial Interests from the Authority issuing written notification rejecting the Products. If Rejected Products are not collected within Redacted Under FOIA Section 43(2), Commercial Interests of the Authority issuing written notification rejecting the Products, the Authority may return the Rejected Products at the Supplier's risk and expense, for the avoidance of doubt which includes the cost of transportation, and charge the Supplier for the cost of storage from the expiry of Redacted Under FOIA Section 43(2), Commercial Interests from the date of notification of rejection.

8.7. Where the Authority rejects any Products in accordance with Clauses 8.3 and/or 8.9 the Supplier shall notify the Authority promptly of the delivery timeframe of the replacement Product, which timeframe shall not impact the Delivery Schedule of non-replacement Product, and the Authority may by written notice cancel its purchase obligations in relation to such quantity of Rejected Products for which replacement Product is: Redacted Under FOIA Section 43(2), Commercial Interests

8.8. The Authority shall be entitled to charge the Supplier for any Loss Costs incurred by the Authority and/or any Administering Entity and/or Devolved Administration as a result of any Defective Products provided that the Authority and/or the Administering Entity and/or Devolved Administration, as appropriate, shall use its reasonable endeavours to mitigate the same. The Supplier shall pay such Loss Costs to the Authority within thirty (30) days of the date of the Authority's invoice for the same.

8.9. Without prejudice to any other provisions of this Agreement or any other warranties or guarantees applicable to the Products supplied and subject to Clause 8.10, if at any time following the date of the delivery or collection of any Products, all or any part of such Products are found by the Authority to be Defective Products, provided that such finding could not reasonably have been made upon such inspection as set forth in Clause 8.2, the Supplier shall, at the Authority's discretion:

8.9.1. upon written request and without charge, promptly (and in any event within Redacted Under FOIA Section 43(2), Commercial Interests or such other time agreed by the Parties in writing acting reasonably) remedy the deficiency by replacing such Defective Products; or

8.9.2. upon written notice of rejection from the Authority, treat such Defective Products as Rejected Products in accordance with Clauses 8.4 to 8.7.

8.10. No failure to make a complaint at the time of the delivery or collection nor any other act or omission of the Authority including in particular taking delivery or collection, keeping a sample, inspection of or payment for any Products by the Authority shall constitute acceptance, waiver or approval of the Products or limit the Authority's right subsequently to reject Products should such Products be Defective Products.

8.11. The Supplier shall be relieved of its liabilities under Clauses 8.4 to 8.7 (inclusive) and/or Clause 8.9 to the extent only that the Products are damaged, there are defects in the Products and/or the Products fail to comply with the requirements of this Agreement due, in each case, to any acts or omissions of the Authority.

8.12. Where the Supplier is required by Law, Guidance and/or Good Industry Practice to order a product recall in respect of the Product ("**Requirement to Recall**"), save for in circumstances where the Product has been transferred, Used, donated or resold

outside of the United Kingdom under Clause 6.18 in a country or other territory where there is: (i) no valid marketing authorisation for the Product; or (ii) without prejudice to what is stated under Clause 13.6.8 (i), a valid marketing authorisation for the Product but where arrangements satisfactory to Supplier regarding pharmacovigilance have not been entered into, the Supplier shall:

8.12.1. promptly (taking into consideration the potential impact of the continued use of the Products on patients, service users and the Authority as well as compliance by the Supplier with any regulatory requirements) notify the Authority in writing of the recall together with the circumstances giving rise to the recall;

8.12.2. from the date of the Requirement to Recall treat the Products the subject of such recall as Defective Products in accordance with Clause 8.9;

8.12.3. consult with the Authority as to the most efficient method of executing the recall of the Products and use its reasonable endeavours to minimise the impact on the Authority of the recall; and

8.12.4. subject to Clause 19, indemnify and keep the Authority indemnified against any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of the Supplier executing such recall, provided, for the avoidance of doubt, that to the extent such losses, damages, costs, expenses, claims or proceedings apply to any death or personal injury suffered by any person, where such death or personal injury arises or results or allegedly arises or results from the Product Used by the Authority or any Administering Entity or Devolved Administration, the provisions of Clause 18.1 shall apply.

9. BUSINESS CONTINUITY

9.1. Throughout the duration of this Agreement, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees such Business Continuity Plan details and will continue to detail robust arrangements the Supplier has and will retain in place with third parties regarding continuity of manufacturing and supply, including the supply of raw materials and utilities and delivery of the Product during a Business Continuity Event.

9.2. The Supplier shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every twelve (12) months. The Supplier shall provide to the Authority summaries of its Business Continuity Plan and summaries of the test reports and improvement plans as evidence that the Supplier tests its Business Continuity Plan at reasonable intervals and seeks improvement. The Supplier shall provide to the Authority a summary of any updated or revised Business Continuity Plan within twenty-one (21) days of any material update or revision to the Business Continuity Plan. The Supplier shall provide to the Authority full copies of its Business Continuity Plan, test reports and improvement plans upon written request by the Authority. The Authority may also view the detail of the Business Continuity Plan at any of the Manufacturing Facilities and suggest amendments to the Business Continuity Plan to the Supplier at any time. Where the Supplier, acting reasonably, deems such suggestions made by the Authority to be relevant and appropriate, the Supplier will incorporate into the Business Continuity Plan all such suggestions made by the Authority in respect of such Business Continuity Plan. Should the

Supplier not incorporate into such Business Continuity Plan any suggestion made by the Authority, it will explain to the Authority the reasons for not doing so. For the avoidance of doubt, the Authority shall only be entitled to receive summaries of, full copies of and/or view the Business Continuity Plan relating to the manufacture of the Products which are the subject of this Agreement and not to other products of the Supplier or to the Supplier's wider business processes not relating directly to the supply of the Products.

9.3. Should a Business Continuity Event occur at any time, the Supplier shall implement and comply with its Business Continuity Plan and provide regular written reports to the Authority on such implementation.

9.4. In the event of a Business Continuity Event other than a Pandemic, the Parties may agree as appropriate a revised Delivery Schedule and review and update this at weekly intervals.

9.5. During a Business Continuity Event, the Supplier shall use all reasonable endeavours to fulfil its obligations to supply the Volume in accordance with the Delivery Schedule and the provisions of this Agreement (including the price for the Product set out at Schedule 3) shall apply equally to all Doses of the Product supplied by the Supplier in accordance with this Clause 9.5.

9.6. Where a British, European or international standard relating to business continuity is specified in Schedule 9, the Supplier shall present in Schedule 9 its Business Continuity Plan compared to such standard identifying where and how it differs.

10. CONTRACT MANAGEMENT, PERFORMANCE AND REVIEW

10.1. The Parties shall comply with the requirements of Schedule 8 (Contract Management).

10.2. The Supplier confirms and agrees that authorised senior representatives of the Supplier shall attend all of the Contract Review Meetings in accordance with Schedule 8.

10.3. The Supplier confirms and agrees that the Supplier's senior representatives attending the Contract Review Meetings shall have the authority to make decisions regarding this Agreement.

10.4. Throughout each Preparedness Phase and during a Pandemic, the Supplier shall keep the Authority fully up to date regarding all of its discussions with the Licensing Authority and their outcome.

10.5. During a Pandemic the Supplier shall provide to the Authority a weekly online report on Monday each week. The details of the report and format shall be agreed in the Contract Review Meetings during the Initial Phase but shall, as a minimum, include the details for each component of the Product as set out in Part B of Schedule 8.

10.6. The Supplier shall comply fully with the provisions of Schedule 6 (Key Performance Indicators).

10.7. Following completion of delivery of the Volume in each Pandemic, the Supplier will meet with the Authority to review its performance in meeting its obligations under this Agreement.

10.8. The Supplier shall comply with the notification, reporting and management information requirements referred to in Schedule 15 (Management Information Schedule).

11. REGULATORY AND INFORMATION REQUIREMENTS

11.1. The Supplier shall maintain, and no later than any date on which it would otherwise expire, obtain a renewal of the Marketing Authorisation in accordance with the provisions of the Human Medicines Regulations 2012 (SI 2012/1916) and, where applicable, Directive 2001/83 and/or Regulation 726/2004 and/or any amended and/or successor legislation applicable to the UK or any part of it from time to time. This obligation shall continue to apply after the expiry or termination of this Agreement until the earlier of: (i) such time as the Authority notifies the Supplier in writing that it has used or disposed of all Doses of the Product supplied under this Agreement; and (ii) the expiry date of the last to expire of the Doses of the Product.

11.2. The Supplier shall promptly, and in any event within two (2) Business Days of becoming aware of the issue, inform the Authority in writing if it knows or believes there to be any delay or other problem with the Marketing Authorisation or its renewal.

11.3. If:

11.3.1. the Marketing Authorisation is withdrawn by the Licensing Authority for reasons relating to the safety or efficacy of the Product , save to the extent such reasons: (i) are attributable to the Seed Virus; and (ii) cannot be shown to be within the control of the Supplier;

11.3.2. the Marketing Authorisation is suspended by the Licensing Authority for a period in excess of one (1) month for reasons relating to the safety or efficacy of the Product, save to the extent such reasons: (i) are attributable to the Seed Virus; and (ii) cannot be shown to be within the control of the Supplier;

11.3.3. the Marketing Authorisation is not renewed by the Licensing Authority following its expiry for a period in excess of one (1) month for reasons relating to the safety or efficacy of the Product, save to the extent such reasons: (i) are attributable to the Seed Virus; and (ii) cannot be shown to be within the control of the Supplier; or

11.3.4. Redacted Under FOIA Section 43(2), Commercial Interests

11.4. Notwithstanding what is stated under sub-Clause 11.3.4.1, should:

11.4.1. the Authority have had the Product approved for supply from Great Britain to Northern Ireland under NIMAR; or

11.4.2. the issuance of and jurisdiction over the Marketing Authorisation for the Pandemic Preparedness Vaccine applicable to Northern Ireland come under the authority of the MHRA,

then, as from the date thereof, the relevant ground set forth under sub-Clause 11.3.1 through 11.3.3 shall apply with regard to the MHRA only.

11.5. If, following the placing of an Order, the Marketing Authorisation concerned is not

maintained by the Supplier, then the Authority shall be entitled to cancel the relevant part of the Order or remaining Volume under the relevant part of the Order as appropriate.

11.6. The Supplier shall:

11.6.1. reply promptly in writing to all enquiries and complaints by the Authority relating to the Use, effective administration, quality, performance and durability of the Product;

11.6.2. to the extent relevant to the performance of this Agreement, ensure that the Authority is kept aware at all times of all data or information obtained by the Supplier, whether in clinical trials or otherwise, or any other matters in each case relating to the safety and/or efficacy of the Product, including the balance of risk and benefits of using the Product. The Supplier shall cooperate with the Authority and the Licensing Authority in investigating such data, information or other matters and shall keep the Authority up to date as to the outcome of such investigations;

11.6.3. as soon as possible, and in any event within seven (7) days of becoming aware of the same, inform the Authority in writing and provide full details of any claim brought by any third party in relation to the Product (including any claim or threatened claim of infringement relating to the Intellectual Property Rights in the Product) and provide regular updates to the Authority on the status of and material developments in any such claim;

11.6.4. without prejudice to Clause 11.6.2, should the Supplier become aware of an actual or suspected adverse reaction to the Product which is not described in the Summary of Product Characteristics, promptly inform the Authority in writing and in any event within seven (7) days of becoming aware of the same and provide regular updates to the Authority on any material developments relating to such adverse reaction; and

11.6.5. when attending the Authority's or any other relevant premises, procure that its employees and agents shall in the performance of this Agreement comply with all relevant health and safety policies and working practices in force within the Authority's or such other premises from time to time (including smoking and alcohol consumption policies) where the Supplier, its employees and agents have been informed in advance by the Authority or where notices of such policies and working practices are reasonably displayed at the relevant premises.

12. QUALITY ASSURANCE

12.1. The Supplier must comply with the terms of its Marketing Authorisation and the Manufacturing Licence. The Supplier must manufacture the Product in accordance with Good Manufacturing Practice.

12.2. The Supplier shall maintain the Manufacturing Licence and all other licences necessary for the manufacture of the Product during the Term and shall not make any material changes (including any changes which shall or may have an impact on the dose regimen, age range for use of the Product, indication, safety profile and/or quality or use of the Product) to the same or to the Specification or the Supplier's quality assurance system in relation to the Product without:

12.2.1. where such material change is to be made in the Preparedness Phase, notifying the Authority in writing in advance of its intention to implement such change and giving the Authority the opportunity to make representations to the Supplier as soon as possible and in any event within ten (10) Business Days of receipt by the Authority of notice that the Supplier intends making such material change, such notice to include details of the consequences which will follow such change being implemented;

12.2.2. where such material change is to be made during a Pandemic, notifying the Authority in writing promptly of the relevant change and details of any material consequences which will follow such change being implemented and giving the Authority the opportunity to make representations to the Supplier within one (1) Business Day of receipt by the Authority of notice that the Supplier intends making such material change; and

12.2.3. the Licensing Authority formally approving such change.

In the event that the Authority has not formally approved such planned changes within the periods set out in this Clause 12, the Supplier shall be free to make such changes without further reference to the Authority or delay if the Licensing Authority has formally approved such change.

12.3. The Supplier shall, at the Supplier's cost, submit sample Doses of the Product from each Batch of the Product to the OMCL(s) named on the Marketing Authorisation for quality assessment and Batch release prior to delivery of the Batch concerned to the Authority. Although the Product may undergo quality assurance assessment, such assessment shall not affect the Supplier's obligations under this Agreement.

13. WARRANTIES

13.1. The Supplier warrants and undertakes that, with the exception of Product supplied to the Authority at the Authority's request under the terms of Schedule 4 and/or Schedule 12 respectively but including unlicensed Product in respect of which a Variation of the Marketing Authorisation is subsequently granted as from the date of the grant of such Variation:

13.1.1. all Doses of the Product will comply with the Specification and the Marketing Authorisation;

13.1.2. it will manufacture the Product in accordance with Good Manufacturing Practice;

13.1.3. the Yield Assumption (as defined in Schedule 5) is based on the most up to date information available to the Supplier as at the Effective Date on the likely Actual Yield (as defined in Schedule 5) which will be obtained, and the Supplier shall promptly notify the Authority in writing in the event of any material change in such information;

13.1.4. the Product is licensed by the Licensing Authority for the treatments and purposes as referred to in the Specification and this Agreement;

13.1.5. the information submitted to support the Marketing Authorisation was and is at the Effective Date valid and accurate;

13.1.6. all Doses of the Product will have at least the shelf life referred to at Clause

6.3.3;

13.1.7. its Business Continuity Plan is sufficient to ensure continuity of supply of the Product to the Authority in accordance with this Agreement in the event of any failure at one or more Manufacturing Facilities including emergency maintenance work and/or if any problems or issues arose in relation to the filling, packaging and finishing of the Product;

13.1.8. it will establish and maintain the UK Manufacturing Capability in accordance with any relevant timescales referred to in this Agreement; and

13.1.9. unless otherwise approved by the Authority in writing in accordance with the terms of this Agreement, it will UK Manufacture all Doses of the Products.

13.2. The Supplier warrants and undertakes that the Supplier shall comply with Good Industry Practice and all Laws, Guidance and regulations applicable to the Product, including relevant provisions of:

13.2.1. Directive 2001/83;

13.2.2. Regulation 726/2004;

13.2.3. all Laws, regulations, guidelines, and Guidance implementing the legislation referred to in Clause 13.2.1 and Clause 13.2.2 within the United Kingdom or any part of it;

13.2.4. any guidelines or directions or like documents that may be published during the Term by the Licensing Authority and are applicable to the Product at the time of manufacture;

13.2.5. the Medicines Acts 1968 (c.67) and 1971 (c.69) and the regulations made thereunder in respect of the sale, supply, importation, manufacture or assembly of the Product;

13.2.6. Human Medicines Regulations 2012 (SI 2012/1916);

13.2.7. Good Manufacturing Practice; and

13.2.8. Directive 2003/94/EC.

13.3. Without prejudice to the Supplier's obligation to comply with all applicable Law and Guidance, where the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of the Products under this Agreement relates to medical devices and/or medicinal products (both as defined under any relevant Law and Guidance), the Supplier warrants and undertakes that it will comply with any such Law and Guidance relating to such activities in relation to such medical devices and/or medicinal products. In particular, but without limitation, the Supplier warrants that:

13.3.1. at the point such Products are supplied to the Authority, all such Products which are medicinal products shall have a valid Marketing Authorisation as required by Law and Guidance in order to supply the Products to the Authority and that all relevant authorisation, labelling, registration, approval and documentation requirements as required under Law and Guidance relating to the sale, manufacture, assembly, importation, storage,

distribution, supply or delivery of such Products shall have been complied with. Without limitation to the foregoing provisions of this Clause 13.3, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of any required valid Marketing Authorisation, and evidence of any other authorisations, labelling, registrations, approvals or documentation required; and

13.3.2. it shall maintain and, no later than any due date when it would otherwise expire, obtain a renewal of any authorisation, registration or approval (including without limitation UKCA and CE marking and/or Marketing Authorisation) required in relation to the Products in accordance with Law and Guidance until the expiry date of the last to expire of the Doses of the Product or the Authority notifies the Supplier in writing that it has used or disposed of all units of the Products supplied under this Agreement.

13.4. The Supplier further warrants and undertakes that:

13.4.1. it has the right and authority to enter into this Agreement and that it has the capability and capacity to fulfil its obligations under this Agreement;

13.4.2. all information included within the Supplier's response to the Invitation to Submit Final Tenders and all accompanying materials is accurate;

13.4.3. it is a properly constituted limited liability company and that it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under this Agreement and the documents referred to therein;

13.4.4. there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Supplier;

13.4.5. there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into this Agreement; and

13.4.6. all necessary actions to authorise the execution of and performance of its obligations under this Agreement have been taken before such execution.

13.5. The Supplier further warrants and undertakes that the Supplier shall:

13.5.1. carry out its obligations under this Agreement, including the Preparatory Activities and Preparatory Pandemic Work, using all reasonable skill and care;

13.5.2. ensure that the capacity which is the subject of the Manufacturing Commitment is available for the benefit of the Authority in the event of a Pandemic;

13.5.3. in the event of a Declaration of a Pandemic, be able to deliver the Total Allocated Volume in the weekly quantities determined in accordance with the Delivery Schedule;

13.5.4. promptly respond to any requests for information regarding the Agreement that the Authority may reasonably make;

13.5.5. ensure that all information provided at or in advance of the Contract Review Meetings, any responses to requests from the Authority for information, the Business Continuity Plan and all relevant information accompanying the Product are and will be in English;

13.5.6. inform the Authority in writing forthwith upon becoming aware of any issue that may impact upon the Supplier's ability to manufacture and supply the Product and during the Preparedness Phase provide to the Authority within two (2) weeks thereof and to the Authority's reasonable satisfaction, the Supplier's proposals for resolving such issue and ensuring the Supplier will be able to manufacture and supply the Product in accordance with this Agreement. During a Pandemic the Supplier will, at the request of the Authority, provide a daily report to the Authority on its continuing actions to resolve any such issue;

13.5.7. have in place enforceable commercial contracts with its suppliers, sub-contractors, agents and other relevant third parties and in the event of such suppliers, sub-contractors, agents and third parties being unable or unwilling to fulfil their obligations to the Supplier, the Supplier shall promptly seek to enforce such commercial contracts;

13.5.8. in an event of Force Majeure, use its best endeavours to appoint alternative suppliers, sub-contractors, agents or other third parties, if possible, where the existing suppliers, sub-contractors, agents or other third parties are unable to fulfil their obligations to the Supplier;

13.5.9. if during the Pandemic public supplies are threatened, work with the appropriate authority to facilitate continuity of such supply; and

13.5.10. put in place and maintain appropriate security measures as detailed in the Business Continuity Plan to enable it to perform its obligations under this Agreement and where maintenance of Law and order is necessary for the fulfilment of such obligations use its best endeavours to secure the support of the appropriate public authority thereto.

13.6. The Supplier further warrants and undertakes that:

13.6.1. the Supplier will, in a Pandemic until such time as the Supplier has fulfilled all Orders which the Authority is entitled to place in respect of such Pandemic (or such Orders have been cancelled in accordance with this Agreement), operate its Manufacturing Facility at full capacity, provided that where the relevant Manufacturing Facility is shared between the Product and other products, this Clause 13.6.1 shall apply solely to those elements of such Manufacturing Facility which are required to be allocated to the manufacture of the Product at the outset of the Pandemic;

13.6.2. the Supplier's ability to meet the Manufacturing Commitment will not be impacted by the requirements of any other countries for Pandemic vaccine. The Supplier shall promptly notify the Authority in the event that it becomes aware of any such impact or potential impact during the Term;

13.6.3. the Manufacturing Facilities shall remain at the locations detailed in Schedule 7 throughout the Term;

13.6.4. during a Pandemic, the Supplier shall fulfil, where possible and with the Authority's prior written consent not to be unreasonably withheld or delayed, its contractual obligations from an alternative manufacturing site if a Manufacturing Facility is unavailable, or is producing below the Reserved Capacity;

13.6.5. the Supplier is reserving a weekly percentage of its manufacturing capacity from the Manufacturing Facility for the Authority of Redacted Under FOIA Section 43(2), Commercial Interests in order to deliver the Manufacturing Commitment, and the Supplier shall use that percentage of capacity solely for the benefit of the Authority during a Pandemic until such time as the Supplier has fulfilled all Orders which the Authority is entitled to place in respect of such Pandemic (or such Orders have been cancelled in accordance with this Agreement);

13.6.6. the Manufacturing Facilities are capable of producing a total of Redacted Under FOIA Section 43(2), Commercial Interests of Product per week from the first week of production onwards, based on any assumptions set out in Schedule 5;

13.6.7. should the capacity of the Manufacturing Facility at the then current site(s) of such Manufacturing Facility increase during the Term the Parties will hold good faith discussions as to how the Authority may benefit from such increase during the Term. The total volume of the Product that the Authority is entitled to order under this Agreement shall not change other than pursuant to Clause 5 or Clause 11.5;

13.6.8. Redacted Under FOIA Section 43(2), Commercial Interests

13.6.9. Redacted Under FOIA Section 43(2), Commercial Interests, the Products shall comply with any necessary additional regulatory or pharmacovigilance requirements relating to the Devolved Administration of Northern Ireland so as to allow the Products to be distributed by the Authority to the Devolved Administration of Northern Ireland. For the avoidance of doubt, the Authority shall be responsible for the costs of any tariffs or customs administration that may become applicable to such distribution of the Products from England to Northern Ireland; and

13.6.10. it shall:

13.6.10.1. comply with all relevant Law and Guidance to ensure that there is no slavery or human trafficking in its supply chains; and

13.6.10.2. at all times conduct its business in a manner that is consistent with any Anti-Slavery Policy of the Authority and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier's compliance with this Clause 13.6.10 and/or as may be requested or otherwise required by the Authority in accordance with its Anti-Slavery Policy.

13.7. The Supplier warrants and undertakes to the Authority that, as at the Effective Date, it has notified the Authority in writing of any Occasions of Tax Non-Compliance or any litigation that it is involved in that is in connection with any Occasions of Tax

Non-Compliance. If, at any point during the Term, an Occasion of Tax Non-Compliance occurs, the Supplier shall:

13.7.1. notify the Authority in writing of such fact within five (5) Business Days of its occurrence; and

13.7.2. promptly provide to the Authority:

13.7.2.1. details of the steps which the Supplier is taking to address the Occasion of Tax Non-Compliance and to prevent the same from recurring, together with any mitigating factors that it considers relevant; and

13.7.2.2. such other information in relation to the Occasion of Tax Non-Compliance as the Authority may reasonably require.

13.8. The Supplier warrants and undertakes that, unless otherwise agreed with the Authority, throughout the Term, subject to any Order placed by the Authority or orders placed by third parties in respect of Pandemic influenza vaccine, the Supplier shall be able to and will continue to fulfil any obligations it has to provide the Authority with seasonal influenza vaccine.

13.9. The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that any of the warranties set out in this Clause 13 have been breached or there is a risk that any warranties may be breached.

13.10. If the Supplier is in breach of the warranties granted under this Clause 13, which breach has a materially adverse impact on the Supplier's fulfilment of its material obligations under this Agreement, then, without prejudice to any other right or remedy of the Authority, the Authority shall be entitled to reject and/or return the Products and the Supplier shall, subject to Clause 19, indemnify and keep the Authority indemnified against any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such breach, provided, for the avoidance of doubt, that to the extent such losses, damages, costs, expenses, claims or proceedings apply to any death or personal injury suffered by any person, where such death or personal injury arises or results or allegedly arises or results from the Product Used by the Authority or any Administering Entity or Devolved Administration, the provisions of Clause 18.1 shall apply.

13.11. Any warranties provided under this Agreement are both independent and cumulative and may be enforced independently or collectively at the sole discretion of the enforcing Party.

14. PRICE AND PAYMENT

14.1. The Contract Price shall be calculated as set out in Schedule 3.

14.2. The Contract Price shall Redacted Under FOIA Section 43(2), Commercial Interests unless otherwise stated in Schedule 3 and is inclusive of any royalties, licence fees, packaging, storage by the Supplier and the cost of delivery to the Authority or the Authority's storage provider or distribution agent or Authorised Agent, or similar expenses connected with the Product, or in respect of making, importing, use or exercise by the Supplier of any invention or design or the supply of any essential

element of any inventions for the purpose of performing this Agreement.

14.3. Save as otherwise provided in this Clause 14, any elements of the Contract Price relating to the delivery or collection of the Product may be invoiced monthly in arrears following the end of the month in which the relevant Product was delivered / collected. The Pandemic Preparedness Fee shall be payable Quarterly in arrears in four equal instalments, save that it will not be payable in respect of any period during which there is a Pandemic. Therefore, during any Contract Years in which there is Pandemic, the Pandemic Preparedness Fee shall be payable on a pro-rata basis (e.g. if there is a Pandemic covering six months of the relevant Contract Year, the Pandemic Preparedness Fee Redacted Under FOIA Section 43(2), Commercial Interests and any Quarterly instalments shall be adjusted accordingly. All valid invoices shall be paid within thirty (30) days of receipt by the Authority.

14.4. Where any element of the Contract Price is Redacted Under FOIA Section 43(2), Commercial Interests, such element shall Redacted Under FOIA Section 43(2), Commercial Interests:

14.4.1. Redacted Under FOIA Section 43(2), Commercial Interests

14.4.2. Redacted Under FOIA Section 43(2), Commercial Interests.

14.5. The Supplier shall issue a Value Added Tax invoice to the Authority for the relevant Doses of the Product following their delivery to or collection by the Authority in accordance with Clause 14.3. All invoices shall be addressed to NHS Supply Chain, West Way, Cotes Park Industrial Estate, Alfreton, Derbyshire, DE54 4QJ. Each invoice shall contain the following information: the Authority's order number, the consignee and the description and quantity of the Product concerned. An invoice may be submitted electronically where it complies with the standard on electronic invoicing. For these purposes, an electronic invoice complies with the standard on electronic invoicing where it complies with the European standard and any of the syntaxes published in Commission Implementing Decision (EU) 2017/1870.

14.6. In the event of late payment by either Party of any sums due to the other Party under this Agreement, the latter Party shall be entitled to charge interest on such outstanding sums in accordance with the Late Payment of Commercial Debts (Interest) Act 1998 (c.20).

14.7. The Authority reserves the right to deduct from any monies due to the Supplier any monies due to the Authority from the Supplier under this Agreement.

14.8. No payment will be made for containers, pallets, crates or packing materials of any description, except by special arrangement agreed in writing by both Parties.

14.9. The Supplier shall provide such management information as the Authority may request from time to time within seven (7) days of the date of the request. The Supplier shall supply the management information to the Authority in such form as may be specified by the Authority and, where requested to do so, the Supplier shall also provide such information to any Contracting Authority whose role it is to analyse such management information in accordance with UK government policy (to include, without limitation, for the purposes of analysing public sector expenditure and planning future procurement activities) (**"Third Party Body"**). The Supplier confirms and agrees that the Authority may provide the Third Party Body with information relating to the Product and any payments made under this Agreement.

14.10. Where the Supplier and/or the Authority provide the management information to a Third Party Body pursuant to Clause 14.9 and such management information is subject to obligations of confidentiality under this Agreement, the Authority shall ensure that any Third Party Body receiving the management information is bound by obligations of confidentiality no less stringent than those which the Authority is bound by under this Agreement in relation to such confidential management information.

14.11. Upon receipt of management information supplied by the Supplier to the Authority and/or the Third Party Body or by the Authority to the Third Party Body, the Authority and the Supplier hereby consent to the Third Party Body:

14.11.1. storing and analysing the management information and producing statistics; and

14.11.2. sharing the management information or any statistics produced using the management information with any other Contracting Authority.

14.12. In the event that the Third Party Body shares the management information or any other information provided under Clause 14.9, any Contracting Authority receiving the management information shall, where such management information is subject to obligations of confidence under this Agreement, be informed of the confidential nature of that information and shall be requested not to disclose it to anybody who is not a Contracting Authority (unless required to do so by Law).

14.13. The Authority may make changes to the management information which the Supplier is required to supply and shall give the Supplier at least one (1) month's written notice of any changes.

14.14. Within seven (7) days of each anniversary of the Effective Date, the Supplier shall provide to the Authority a written report summarising all business transacted pursuant to this Agreement in the preceding twelve (12) months, including a breakdown of all Doses of the Product supplied on a month by month basis and which sets out Batch numbers, quantities, and expiry date of all Doses of the Product supplied.

14.15. When the final invoice is to be issued in respect of any Order, the Supplier shall perform a Reconciliation exercise. As part of such Reconciliation, the Supplier shall:

14.15.1. reduce such invoice by the value of any Service Credit applying to the relevant Pandemic; and

14.15.2. add to such invoice any applicable Risk-Sharing Fee which falls due under the terms of this Agreement.

14.16. Where the application of any deductions under Clause 14.15 results in a credit falling due to the Authority, the Supplier shall pay the relevant sums to the Authority within thirty (30) days.

14.17. Where it becomes clear that no further invoice will be issued in respect of the relevant Pandemic and a Reconciliation has not yet been performed, the Supplier shall promptly perform a Reconciliation and invoice the Authority or pay any relevant sums to the Authority, as applicable, within thirty (30) days.

14.18. The Supplier shall promptly supply full details of the basis of each Reconciliation to

the Authority in writing.

15. TERM AND TERMINATION

15.1. This Agreement shall commence on the Effective Date and continue for the Term unless terminated earlier in accordance with the terms of this Agreement.

15.2. The Authority shall be entitled to extend the Term with the written consent of the Supplier, such consent not to be unreasonably withheld, in fixed increments of twenty four (24) months by submitting a written request for the consent of the Supplier no less than twelve (12) months prior to the date on which this Agreement would otherwise have expired, and thereafter nine (9) months before the expiry of any extension period. The Supplier confirms and agrees that if the Supplier has not received such a request for consent to extend from the Authority fifteen (15) months before any expiry date of this Agreement or any extension period, the Supplier will notify the Authority in writing seeking confirmation of whether the Authority intends to so extend this Agreement. The Authority may require one or more further extensions to the Term under and subject to this Clause 15.2 provided that the total Term shall not exceed ten (10) years.

15.3. In the case of a breach of any of the terms of this Agreement by either Party that is capable of remedy (including, without limitation any breach of any KPI (as defined in Schedule 6) and any breach of any payment obligations, under this Agreement), the non-breaching Party may, without prejudice to its other rights and remedies under this Agreement, issue a written notice to the Party in breach of such breach and shall allow the Party in breach the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Party in breach ("**Remedial Proposal**") before exercising any right to terminate this Agreement in accordance with Clause 15.4. In order to become effective, such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and such Remedial Proposal, if agreed with the non-breaching Party, must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to put forward and agree a Remedial Proposal with the non-breaching Party in relation to the relevant default or breach within a period of two (2) Business Days (or such other period as the non-breaching Party may agree in writing) from written notification of the relevant default or breach from the non-breaching Party shall mean that the Party in breach may not (unless agreed with the non-breaching Party in writing) use the opportunity to have a Remedial Proposal agreed. Any failure by the Party in breach to:

15.3.1. comply with a Remedial Proposal agreed with the non-breaching Party (including, without limitation, as to its timescales for implementation, which shall be thirty (30) days unless otherwise agreed between the Parties); or

15.3.2. remedy the default or breach notwithstanding the implementation of such Remedial Proposal provided that the agreed timescales of the Remedial Proposal have been allowed for implementation,

shall, provided that the breach to be remedied under the Remedial Proposal is material, be deemed, for the purposes of Clause 15.4.1 to be a material breach of this Agreement by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

15.4. The Authority may terminate this Agreement forthwith by notice in writing to the Supplier:

15.4.1. if the Supplier commits a material breach of any of the terms of this Agreement and: (i) in the case of a breach capable of remedy, if such breach shall not be remedied or made good within thirty (30) Business Days of written notice thereof; or (ii) where a Remedial Proposal has been agreed in respect of such breach, such breach is not remedied in accordance with such Remedial Proposal;

15.4.2. if the Supplier ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise); has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;

15.4.3. [Not Used.]

15.4.4. if the Supplier undergoes a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (c.4) (other than for an intra-group change of control) without the prior written consent of the Authority and the Authority shall be entitled to withhold such consent if, in the reasonable opinion of the Authority, the proposed change of control will have a material impact on the supply of the Product or the reputation of the Authority;

15.4.5. pursuant to and in accordance with (including, for the avoidance of doubt, taking into account such notice period, if any, as stated in) Clause 5.1; Clause 11.3, Clause 20.19; Clause 22; Clause 23.7; Clause 23.9; Clause 30.2; Clause 33.10.2 or Schedule 6;

15.4.6. if the warranty given by the Supplier pursuant to Clause 13.7 is materially untrue, the Supplier commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 13.7 or the Supplier fails to provide details of proposed mitigating factors as required by Clause 13.7 that in the reasonable opinion of the Authority are acceptable;

15.4.7. if the Supplier fails to put in place the UK Manufacturing Capability in accordance with any timescales set out in or agreed in accordance with this Agreement;

15.4.8. Redacted Under FOIA Section 43(2), Commercial Interests or

15.4.9. upon written notice to the Supplier where the Authority has accepted a formal written request by the Supplier to be released from this Agreement

due to the Supplier being successful in another UK government procurement, which has resulted in the Supplier being awarded a contract aimed at superseding this Agreement from a UK government perspective.

15.5. If there has been a material deterioration in the financial circumstances of the Supplier and/or any third party guaranteeing the obligations of the Supplier under this Agreement and/or any Material Sub-contractor of the Supplier when compared to any information provided to and/or assessed by the Authority as part of any procurement process or other due diligence leading to the award of this Agreement to the Supplier or the entering into a Sub-contract by the Supplier, the following process shall apply:

15.5.1. the Authority may (but shall not be obliged to) give notice to the Supplier requesting adequate financial or other security and/or assurances for due performance of its material obligations under this Agreement on such reasonable and proportionate terms as the Authority may require within a reasonable time period as specified in such notice;

15.5.2. a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with this Clause 15.5 in accordance with any reasonable timescales specified in any such notice issued by the Authority shall be deemed a breach of this Agreement by the Supplier and shall be referred to and resolved in accordance with the dispute resolution procedure set out in Clause 21; and

15.5.3. a failure to resolve such breach in accordance with such dispute resolution procedure by the end of the escalation stage of such process shall entitle, but shall not compel, the Authority to terminate this Agreement in accordance with Clause 15.4.1, provided that in the case that the material deterioration in the financial circumstances described in the first paragraph of this Clause 15.5 refers to a Material Sub-Contractor, such right to terminate shall not apply if the Supplier notifies the Authority within five (5) days of receipt of notice of termination that it intends to replace such Material Sub-contractor, exercises its reasonable endeavours to agree with the Authority on a plan for the replacement of such Material Sub-contractor and pursues such plan, or, in case the Parties have not been able to agree on a plan, pursues activities with diligence, towards replacement of such Material Sub-contractor with a new Material Sub-contractor.

In order that the Authority may act reasonably in exercising its discretion in accordance with Clause 15.5 the Supplier shall provide the Authority with such reasonable and proportionate up-to-date financial or other information relating to the Supplier or any relevant third party entity upon request.

15.6. The Authority may terminate this Agreement by giving written notice where:

15.6.1. this Agreement has been substantially amended to the extent that the Public Contracts Regulations 2015 (SI 2015/102) require a new procurement procedure; or

15.6.2. the Authority has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 (SI 2015/102) from the procurement procedure leading to the award of this Agreement; or

15.6.3. there has been a material failure by the Supplier and/or one of its Material Sub-contractors or Direct Sub-contractors to comply with its or their legal obligations in the fields of environmental, social or labour Law, provided that in the case that such material failure has been committed by a Material Sub-Contractor or a Direct Sub-contractor, such right to terminate shall not apply if the Supplier notifies the Authority within five (5) days of receipt of notice of termination that it intends to replace such Material Sub-Contractor or Direct Sub-contractor, exercises its reasonable endeavours to agree with the Authority on a plan for the replacement of such Material Sub-contractor or Direct Sub-contractor and pursues such plan, or, in case the Parties have not been able to agree on a plan, pursues activities with diligence, towards replacement of such Material Sub-contractor or Direct Sub-contractor with a new Material Sub-contractor or Direct Sub-contractor, as applicable. Where the material failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the Supplier's Material Sub-contractors or Direct Sub-contractors, the Authority may, in circumstances where the Suppler has not invoked its right to replace such Material Sub-contractor or Direct Sub-contractor, as applicable, in accordance with what is stated above in this Clause 15.6.3, request the replacement of such Material Sub-contractor or Direct Sub-contractor and the Supplier may comply with such request as an alternative to the Authority terminating this Agreement under this Clause 15.6.

15.7. In the event of a Declaration of a Pandemic during the Term as may be extended in accordance with this Agreement, following the final delivery of the Product to and acceptance by the Authority, this Agreement shall continue until the then current expiry date of the Term, subject to any extension under this Clause 15.

15.8. The Supplier shall be entitled to terminate this Agreement forthwith by notice in writing if the Authority fails to pay undisputed invoices for three (3) or more consecutive months.

15.9. The Parties confirm and agree that if the Authority places an Order within the Term as may be extended in accordance with this Agreement the Supplier will supply and deliver the Product so ordered even if the date of such supply and delivery is after the expiry of the Term. In such event this Agreement will apply in its entirety to such Product.

16. POST-TERMINATION PROVISIONS

16.1. Following termination of this Agreement for any reason other than:

16.1.1. effluxion of time;

16.1.2. an inability of the Supplier to supply the Product; or

16.1.3. subject to Clauses 15.8 and 22,

the Authority shall be entitled to place Orders with the Supplier, at the agreed Contract Price, to deliver further Product and the Supplier shall use Commercially Reasonable Endeavours to deliver further Product in accordance with a new and updated Delivery Schedule and on the remaining terms of this Agreement to the extent that they relate to the delivery of Product in such volumes as may be necessary to enable the Authority to meet demand for the Product existing at the

date of termination and for a period of six (6) months thereafter, subject to payment for such Product upon delivery. The Supplier's obligation in this Clause 16.1 is subject to, at the time of the relevant Order: (i) the relevant Manufacturing Facilities continuing to manufacture the Product; (ii) there being sufficient available capacity in the relevant Manufacturing Facilities to accommodate the Order; and (iii) the Supplier's other contractual obligations in respect of the relevant Manufacturing Facilities not preventing supply under the Order.

16.2. In the event of termination pursuant to Clause 11.3, should the Authority inform the Supplier that the Authority no longer requires unused Product, the Supplier shall:

16.2.1. refund to the Authority the price paid for all unused Product delivered to the Authority as at the date of termination and pay such refund to the Authority within thirty (30) days of the date of the Authority's invoice for the same; and

16.2.2. at its own expense, remove all unused Product delivered to the Authority as at the date of termination within fourteen (14) days of the date of notification by the Authority that the Authority wishes to return unused Product. The Authority shall not request the Supplier to collect such Product from a greater number of collection points than the Supplier delivered the Product to. Risk and title in such Product shall pass to the Supplier on the date of such notification by the Authority and if the Supplier fails to remove the Product within fourteen (14) days the Authority may return the Product at the Supplier's expense.

16.3. In the event of termination of this Agreement under Clauses 15.4.1, 15.4.2 , 15.4.4, 15.4.5, 15.4.6, Clause 20.19, Clause 30.2.1 or Schedule 6, and without prejudice to any other right or remedy of the Authority and/or any Administering Entity and/or any Devolved Administration, the Authority and/or any Administering Entity and/or any Devolved Administration shall be entitled to claim the Loss Costs from the Supplier arising as a result of such termination provided that the Authority and/or Administering Entity and/or Devolved Administration, as appropriate, shall use its/their reasonable endeavours to mitigate the same. The Supplier shall pay such Loss Costs to the Authority within thirty (30) days of the date of the Authority's invoice for the same.

16.4. Termination of this Agreement for whatever reason shall not affect the enforceability of provisions herein expressed to operate following termination and in any event shall be without prejudice to any subsisting right remedy or obligation of either Party.

16.5. Following termination of this Agreement, where there has been any Product supplied to the Authority under the Agreement, the Supplier shall continue to meet its legal and regulatory obligations in respect of the Product, including without limitation obligations relating to patient safety and pharmacovigilance.

16.6. Following termination of this Agreement, the Authority shall, without limiting what is stated in Clause 5.6, make any payments due to the Supplier pursuant to Clause 5.6.

16.7. Upon termination of this Agreement for any reason Clauses 1, 7, 11.1, 11.2, 11.3, 11.6.2, 11.6.3, 11.6.4, 13, 16, 17, 18, 19, 20, 21, 23, 25.3, 25.7 and 26 to 42 shall continue in force.

17. INTELLECTUAL PROPERTY RIGHTS

17.1. The Supplier warrants, represents and undertakes to the Authority that either it is the sole proprietor and legal and beneficial owner of all Intellectual Property Rights in the Product or it is licensed by the relevant owners to manufacture and supply the Product in accordance with this Agreement, and shall ensure that it remains the owner and/or licensee (as applicable) of the Intellectual Property Rights in the Product throughout the Term.

17.2. Unless specified otherwise in the Specification, the Supplier hereby grants to the Authority, for the life of the use of Products by the Authority, an irrevocable, royalty-free, non-exclusive licence of any Intellectual Property Rights required for the purposes of receiving and Using, and to the extent necessary to receive and Use, the Products (to include any associated technical or other documentation and information supplied or made accessible to the Authority in any media) in accordance with this Agreement.

17.3. The Supplier warrants and represents that any receipt and Use of the Product by the Authority or any Administering Entity and/or any Devolved Administration in accordance with this Agreement shall not infringe any Intellectual Property Rights of any third party.

17.4. Subject to Clause 19, the Supplier shall indemnify and hold harmless the Authority and any Administering Entity and any Devolved Administration against all claims, liabilities, losses, damages, costs (including legal costs) and expenses incurred in connection with any claim by any party that its Intellectual Property Rights in the Product have been infringed as a result of the manufacture or supply of the Product under this Agreement or the Use of the Product.

18. PRODUCT LIABILITY

18.1. The Supplier shall indemnify and hold harmless each of the Indemnified Parties against all Product Liability Indemnity Claims up to a maximum of the Product Liability Indemnity Cap.

18.2. The Authority shall indemnify and hold harmless the Supplier against:

18.2.1. all Product Liability Indemnity Claims in excess of the Product Liability Indemnity Cap; and

18.2.2. all Exempt Claims.

18.3. The Supplier shall indemnify and hold harmless each of the Indemnified Parties in full against all Additional Supplier Product Liability Claims. For the avoidance of doubt, the Product Liability Indemnity Cap shall not apply in respect of Additional Supplier Product Liability Claims.

18.4. The Authority shall use its reasonable endeavours to ensure that the use of the Product in respect of an influenza virus which is the subject of a Pandemic shall fall within the scope of a relevant personal injury compensation scheme under the Vaccine Damage Payments Act 1979 (c.17).

18.5. In this Clause 18:

18.5.1. "**Additional Supplier Product Liability Claim**" means any Claim which arises or results or allegedly arises or results from (i) production, storage and/or delivery of the Product that does not comply with Good Manufacturing

Practice (including quality control); or (ii) non-conformity of the Product with the Specification.

18.5.2. "**Claim**" means claims, liabilities, losses, damages, costs (including legal costs) and expenses in respect of or relating directly or indirectly to any death or personal injury suffered by any person, where such death or personal injury arises or results or allegedly arises or results from the Product supplied under this Agreement and Used by an Indemnified Party;

18.5.3. "**Exempt Claim**" means any Claim, to the extent that such Claim: (i) is attributable to a Defective Product, where such Defective Product ought to have been discovered by the Authority's inspection in accordance with Clause 8.2; or (ii) arises or results directly from the Use and/or storage by any Indemnified Party of the Product supplied under this Agreement in contravention of any requirements set out in the Summary of Product Characteristics (including storage or administration requirements set out in the Summary of Product Characteristics).

18.5.4. "**Indemnified Party**" means any of the Authority, any Administering Entity and/or any Devolved Administration;

18.5.5. "**Product Liability Indemnity Cap**" means an amount equivalent to Redacted Under FOIA Section 43(2), Commercial Interests ordered from the Supplier and paid for by the Authority; and

18.5.6. "**Product Liability Indemnity Claims**" means all Claims, save to the extent that any Claim is either an Exempt Claim or an Additional Supplier Product Liability Claim.

19. LIMITATION OF LIABILITY

19.1. Nothing in this Agreement shall exclude or restrict the liability of either Party:

19.1.1. for death or personal injury resulting from its negligence; or

19.1.2. for fraud or fraudulent misrepresentation; or

19.1.3. in any other circumstances where liability may not be limited or excluded under any applicable Law.

19.2. Nothing in this Agreement shall exclude or restrict the liability of the Supplier under Clause 17.4 or Clause 18.1 (except as otherwise provided for in such Clause).

19.3. Subject to Clauses 19.1 and 19.2, the liability of the Supplier under this Agreement shall be limited to:

19.3.1. with regard to claims that do not fall under Clause 19.3.2, an amount equivalent Redacted Under FOIA Section 43(2), Commercial Interests applicable at the time of the occurrence of the event from which the claim emanates; and

19.3.2. with regard to claims that relate to an Order placed by the Authority under this Agreement (including for these purposes the performance of the Supplier's obligations in relation to such Order and the Products supplied pursuant to such Order), Redacted Under FOIA Section 43(2), Commercial

Interests, less the value of any Doses under such Order which have been cancelled or in respect of which such Order has been reduced hereunder in each case other than for reasons attributable to the Supplier's breach of this Agreement.

Each limitation amount under Clauses 19.3.1 and 19.3.2, respectively, shall apply to all relevant claims in aggregate under Clauses 19.3.1 and 19.3.2, respectively.

19.4. The Authority shall promptly, after receipt of any claim or notification of other circumstances to which an indemnity given by the Supplier in this Agreement may apply, notify the Supplier of such fact and the Supplier shall assume the defence of any relevant claim or legal proceedings. The Authority shall provide the Supplier with all reasonable cooperation requested by the Supplier subject to the Supplier reimbursing the Authority's reasonable costs incurred in providing such cooperation; provided, however, that if the defendants in any such action include both of the Parties and/or the Supplier and an Administering Entity and/or any Devolved Administration and the Authority and/or the relevant Administering Entity and Devolved Administration have reasonably concluded that there may be defences available to it which are different from, additional to, or inconsistent with those available to the Supplier, the Authority and/or the Administering Entity and/or Devolved Administration shall have the right to select and pay for their own separate counsel to participate in the defence of such action on behalf of the Authority or the relevant Administering Entity or any Devolved Administration. In defending any legal proceedings under this Clause 19.4 the Supplier:

19.4.1. shall use appropriately qualified and experienced lawyers;

19.4.2. shall defend any relevant claim robustly and expeditiously; and

19.4.3. shall not make an admission of liability or settle any relevant claim unless the admission or settlement is advised by the lawyer acting in defence of such claim and the Authority has provided its written consent to such admission or settlement, such consent not be unreasonably withheld or delayed.

19.5. In exercising any right to recover any sums in relation to any claims, liabilities, losses, damages, costs and expenses from the Supplier under any indemnity contained in this Agreement, such sums shall be reduced to the extent only that the Authority or any Administering Entity or any Devolved Administration has not taken reasonable steps within its reasonable control to mitigate such claims, liabilities, losses, damages, costs or expenses, whereby not having taken such reasonable steps within its reasonable control to so mitigate shall include having committed a breach of this Agreement, having been negligent or having acted through wilful misconduct, and the direct effect of not taking such steps has been the inflation of such sums. Where the Authority has a right to invoice the Supplier for any sums under this Agreement, prior to issuing such invoice, the Authority shall notify the Supplier of the value of such invoice to allow the Supplier an opportunity to raise any questions the Supplier may have in relation to such sums. Any disputes relating to such sums payable by the Supplier in accordance with this Agreement must be raised by the Supplier within ten (10) calendar days of such notification and shall be dealt with in accordance with Clause 21.

20. CONFIDENTIALITY, FREEDOM OF INFORMATION AND TRANSPARENCY, AND DATA PROTECTION

20.1. In respect of any Confidential Information it may receive directly or indirectly from the other Party ("**the Discloser**") and subject always to the remainder of this Clause 20, each Party ("**the Recipient**") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser's prior written consent, provided that:

20.1.1. the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Effective Date;

20.1.2. the provisions of this Clause 20 shall not apply to any Confidential Information:

20.1.2.1. which is in or enters the public domain other than by breach of this Agreement or other act or omissions of the Recipient;

20.1.2.2. which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;

20.1.2.3. which is authorised for disclosure by the prior written consent of the Discloser;

20.1.2.4. which the Recipient can demonstrate was in its possession without any obligation of confidentiality prior to receipt from the Discloser;

20.1.2.5. which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange; or

20.1.2.6. the disclosure of which is required to ensure the compliance of the Authority or (as the case may be) an Administering Entity or Devolved Administration with any Law including, but not limited to, the Freedom of Information Act 2000 (c.36) ("**FOIA**"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("**Codes of Practice**"), or the Environmental Information Regulations 2004 (SI 2004/3391) ("**Environmental Regulations**").

20.2. The Supplier may only disclose the Authority's Confidential Information to the Supplier's Staff who are directly involved in the performance of the Supplier's obligations under this Agreement, and shall ensure that such Staff are aware of and shall comply with obligations in this Clause 20 as to confidentiality. The Supplier shall not, and shall procure that the Supplier's Staff do not, use any of the Authority's Confidential Information received otherwise than for the purposes of performing the Supplier's obligations in this Agreement. Nothing in this Clause 20 shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable Law. Nothing in this Agreement shall prevent the Authority from disclosing Confidential Information (including the management information obtained under Clause 14.9):

20.2.1. on a confidential basis, to any Contracting Authority. All Contracting

Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority; or

20.2.2. on a confidential basis, to a professional adviser, consultant, supplier or other person engaged by the Authority or by any of the entities described in Clause 20.2.1 (including any benchmarking organisation) for any purpose relating to or connected with this Agreement;

20.2.3. on a confidential basis, to any consultant, contractor or other person engaged by the Authority and/or the Contracting Authority receiving such information, or any person conducting a gateway review or equivalent project review on behalf of the Cabinet Office Major Projects Authority or other relevant body administering such reviews;

20.2.4. to any relevant party for the purpose of the examination and certification of the Authority's accounts;

20.2.5. to any relevant party for any examination pursuant to section 6(1) of the National Audit Act 1983 (c.44) of the economy, efficiency and effectiveness with which the Authority has used its resources;

20.2.6. to the UK Parliament and UK Parliamentary Committees, or if required by any UK Parliamentary reporting requirements; or

20.2.7. on a confidential basis, to a proposed successor body in connection with any proposed, or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Agreement,

and for the purposes of this Agreement, references to disclosure "**on a confidential basis**" shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause 20.2.

20.3. The Supplier acknowledges that the Authority, Administering Entities and Devolved Administrations are or may be subject to the FOIA, Codes of Practice and/or Environmental Regulations or equivalent legislation in their relevant jurisdiction. The Supplier will act in accordance with the FOIA, the Codes of Practice and the Environmental Regulations (and any other applicable codes of practice or Guidance notified to the Supplier from time to time) to the extent that they apply to the Supplier's performance under this Agreement. In no event shall the Supplier respond directly to a Request for Information unless expressly authorised to do so by the Authority.

20.4. The Supplier agrees that:

20.4.1. without prejudice to the generality of Clause 20.3, the provisions of this Clause 20 are subject to the respective obligations and commitments of the Authority and any Administering Entity and/or any Devolved Administration (as the case may be) under the FOIA, the Codes of Practice and the Environmental Regulations;

20.4.2. the decision on whether any exemption applies to a Request for Information of recorded information is a decision solely for the Authority or an

Administering Entity and/or any Devolved Administration (as the case may be); and

20.4.3. where the Authority or an Administering Entity or Devolved Administration is managing a Request for Information as referred to in Clause 20.4.2, the Supplier shall co-operate with the Authority and any Administering Entity and/or Devolved Administration and shall respond within five (5) Business Days of any request by it for assistance in determining how to respond to a Request for Information.

20.5. The Supplier shall:

20.5.1. transfer any Request for Information, to the Authority or an Administering Entity or any Devolved Administration as soon as practicable after receipt and in any event within five (5) Business Days of receiving a Request for Information;

20.5.2. to the extent required by the applicable Law, provide the Authority or an Administering Entity or Devolved Administration with a copy of all information in its possession or power in the form that the Authority or an Administering Entity or Devolved Administration requires within five (5) Business Days (or such other period as the Authority or an Administering Entity or Devolved Administration may specify) of the Authority or an Administering Entity or Devolved Administration requesting that information;

20.5.3. provide all necessary assistance and cooperation as reasonably requested by the Authority or an Administering Entity or Devolved Administration to enable the Authority or an Administering Entity or Devolved Administration to respond to a Request for Information within the time for compliance set out in section 10 of the FOIA; and

20.5.4. not respond directly to a Request for Information addressed to the Authority unless authorised in writing to do so by the Authority.

20.6. The Supplier acknowledges that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA and/or the Environmental Regulations:

20.6.1. the Transparency Reports;

20.6.2. the content of this Agreement, including any changes to this Agreement agreed from time to time, except for any Commercially Sensitive Information; and

20.6.3. the Publishable Performance Information,

(together the "**Transparency Information**") are not Confidential Information.

20.7. The Authority shall be responsible for determining in its absolute discretion whether any of the content of the Agreement is exempt from disclosure in accordance with the provisions of the FOIA and/or the Environmental Regulations.

20.8. Notwithstanding any other term of this Agreement, the Supplier hereby gives its consent for the Authority to publish to the general public the Transparency Information in its entirety (but with any information which is exempt from disclosure

in accordance with the provisions of the FOIA and/or the Environmental Regulations redacted). The Authority shall, prior to publication, consult with the Supplier on the manner and format of publication and to inform the Supplier of its decision regarding any redactions but the Authority shall have the final decision in its absolute discretion.

20.9. The Supplier shall assist and co-operate with the Authority to enable the Authority to publish the Transparency Information, including the preparation of the Transparency Reports in accordance with paragraph 1 of Schedule 16.

20.10. The Authority may, at its sole discretion, redact information from the Transparency Information prior to publishing for one or more of the following reasons:

20.10.1. national security;

20.10.2. Personal Data;

20.10.3. information protected by intellectual property law;

20.10.4. third party confidential information;

20.10.5. IT security; or

20.10.6. prevention of fraud.

20.11. The Authority may consult with the Supplier to inform its decision regarding any exemptions and/or redactions but the Authority shall have the final decision in its absolute discretion. The Supplier shall assist and cooperate with the Authority to enable the Authority to publish this Agreement.

20.12. If the Authority believes that publication of any element of the Transparency Information would be contrary to the public interest, the Authority shall be entitled to exclude such information from publication. The Authority acknowledges that it would expect the public interest by default to be best served by publication of the Transparency Information in its entirety. Accordingly, the Authority acknowledges that it will only exclude Transparency Information from publication in exceptional circumstances and agrees that where it decides to exclude information from publication it will provide a clear explanation to the Supplier.

20.13. The Authority shall publish the Transparency Information in a format that assists the general public in understanding the relevance and completeness of the information being published to ensure the public obtain a fair view on how the Agreement is being performed, having regard to the context of the wider commercial relationship with the Supplier.

20.14. The Authority or an Administering Entity or Devolved Administration may consult the Supplier in relation to any request for disclosure of the Supplier's Confidential Information in accordance with all applicable Guidance.

20.15. The Authority will use all reasonable endeavours to consult the Supplier in relation to any request for disclosure of the Supplier's Confidential Information under the FOIA and, subject to Clause 20.4.2, will take into account any reasonable comment received from the Supplier within five (5) Business Days of consulting with the Supplier.

20.16. This Clause 20 shall remain in force without limit in time in respect of Confidential Information which comprises Personal Data or which relates to a patient, their treatment and/or medical records. Save as aforesaid, this Clause 20 shall remain in force for a period of three (3) years after the termination or expiry of this Agreement.

20.17. The Supplier shall not, without the prior written consent of the Authority, announce or publish any information about this Agreement that has not already been published by the Authority. The Supplier may announce or publish that it has entered into this Agreement and that it has been appointed as a supplier to the Authority of the Product, subject to the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed.

20.18. This Clause 20 is without prejudice to any application of the Official Secrets Acts 1911 to 1989 to any Confidential Information.

20.19. The Supplier shall comply with, and ensure that its Staff comply with, any relevant provisions of: (i) the Official Secrets Acts 1911 to 1989; and (ii) section 182 of the Finance Act 1989 (c.26). In the event that, following written notification from the Authority to the Supplier that the legislation referenced in this Clause 20.19 applies to the subject matter of this Agreement, the Supplier or its Staff fail to comply with this Clause 20.19, the Authority reserves the right to terminate this Agreement by giving notice in writing to the Supplier.

20.20. The Supplier shall comply at all times with the Data Protection Legislation and shall not perform its obligations under this Agreement in such a way as to cause the Authority to breach any of its applicable obligations under the Data Protection Legislation.

21. DISPUTES

21.1. The Supplier confirms to the Authority that it is not aware of any dispute or circumstances likely to give rise to a dispute relating to the production, design, supply or Use of the Product.

21.2. During any dispute, including a dispute as to the validity of the Agreement, it is mutually agreed that the Supplier shall continue its performance of the provisions of the Agreement (unless the Authority requests in writing that the Supplier does not do so).

21.3. If any dispute arises out of the Agreement (other than in relation to any matter in which the Authority has a discretion which is exercised in accordance with the terms of the Agreement and which shall be final and conclusive) the Parties will use all of their respective reasonable endeavours to resolve it by negotiation with any disputes being escalated to the Chief Executive Officers (or equivalent) of each Party to the extent that such disputes cannot otherwise be resolved within fourteen (14) days from the date of any dispute arising. If negotiations fail to resolve such dispute the Parties will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution ("**CEDR**") Model Mediation Procedure or any other model mediation procedure as agreed by the Parties. To initiate mediation a Party shall give notice in writing (a "**Mediation Notice**") to the other Party requesting mediation of the dispute and shall send a copy thereof to CEDR, or an equivalent mediation organisation as agreed by the Parties, asking them to nominate a mediator in the event that the Parties shall not be able to agree such appointment

by negotiation. The mediation shall commence within twenty-eight (28) days of the Mediation Notice being served. Neither Party will terminate such mediation until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour or one Party has failed to participate in the mediation process. Neither Party will commence legal proceedings against the other until thirty (30) days after such mediation of the dispute in question has failed to resolve the dispute. The Authority and the Supplier will co-operate with any person appointed as mediator, providing him with such information and other assistance as he shall require, and will pay his costs, as he shall determine or in the absence of such determination such costs will be shared equally.

21.4. Nothing in this Agreement shall prevent:

21.4.1. the Authority taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with the Product; or

21.4.2. either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party, pending resolution of the relevant dispute in accordance with the CEDR procedure.

22. FORCE MAJEURE

22.1. Subject to Clause 22.2 neither Party shall be liable to the other for any failure to perform all or any of its obligations under the Agreement nor be liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by an event of Force Majeure.

22.2. The Supplier shall only be entitled to rely on an event of Force Majeure and will not be considered to be in default or liable for breach of any obligations hereunder if:

22.2.1. the Supplier has fulfilled its obligations pursuant to Clauses 9.1, 9.2, 9.3 and 9.5; and

22.2.2. the event of Force Majeure does not arise directly or indirectly as a result of any wilful or negligent act or default of the Supplier.

22.3. For the avoidance of doubt, the Parties confirm and agree that a non-influenza Pandemic and a non-influenza epidemic shall each be an event of Force Majeure.

22.4. Where a Party is (or claims to be) affected by an event of Force Majeure, it shall use reasonable endeavours to mitigate the consequences of such an event upon the performance of its obligations under this Agreement, and to resume the performance of its obligations affected by the event of Force Majeure as soon as practicable.

22.5. Where the event of Force Majeure affects the Supplier's ability to perform part of its obligations under the Agreement, the Supplier shall fulfil all such contractual obligations that are not so affected and shall not be relieved from its liability to do so.

[redacted] If either Party is prevented or delayed in the performance of its obligations under this Agreement by an event of Force Majeure, that Party shall immediately serve notice in writing on the other specifying the nature and extent of the circumstances giving rise to its failure to perform and any anticipated delay in performance of its

obligations ("**Force Majeure Notice**"). If the Supplier is the Party prevented or delayed by such event of Force Majeure, it may, at its discretion Redacted Under FOIA Section 43(2), Commercial Interests.

22.7. Subject to service of such Force Majeure Notice, the Party affected by such circumstances shall have no liability for its failure to perform or for any delay in performance of its obligations affected by the event of Force Majeure only for so long as such circumstances continue and for such time after they cease as is necessary for that Party, using reasonable endeavours, to recommence its affected operations in order for it to perform its obligations.

22.8. The Party claiming relief shall notify the other Party in writing as soon as the consequences of the event of Force Majeure have ceased and of when performance of its affected obligations can be resumed.

22.9. Redacted Under FOIA Section 43(2), Commercial Interests

23. RIGHT OF AUDIT, CONFLICTS OF INTEREST AND THE PREVENTION OF FRAUD

23.1. The Supplier shall keep secure and maintain for the Term and seven (7) years thereafter, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Agreement. Where any records could be relevant to a claim for personal injury, such records shall be kept secure and maintained for a period of twenty-one (21) years from the date of expiry or earlier termination of this Agreement.

23.2. The Supplier shall grant to the Authority or its Authorised Agent, such access to those records as they may reasonably require in order to check the Supplier's compliance with this Agreement for the purposes of:

23.2.1. the examination and certification of the Authority's accounts; or

23.2.2. any examination pursuant to section 6(1) of the National Audit Act 1983 (c.44) of the economic efficiency and effectiveness with which the Authority has used its resources,

in so far as such access is compatible with Good Manufacturing Practice.

23.3. The Comptroller and Auditor General of the UK may examine such documents as it may reasonably require which are owned, held or otherwise within the control of the Supplier, and may require the Supplier to provide such oral and/or written explanations as it considers necessary. This Clause 23 does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under section 6(3)(d) and 6(5) of the National Audit Act 1983 (c.44).

23.4. The Authority shall have the right to audit the Supplier's compliance with this Agreement. The Supplier shall permit or procure permission for the Authority or its authorised representative during normal business hours, having given advance notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Agreement. During a Pandemic the Supplier shall permit or procure permission for the Authority or its authorised representative during normal business hours, having given advance notice of no less than one (1) Business Day, access to any premises and facilities, books and records used in the performance of the Supplier's

obligations under this Agreement, should the Authority have reasonable grounds for concern regarding the ability of the Supplier to fulfil its obligations hereunder. In addition to the aforementioned general rights of audit, the Authority will schedule and agree with the Supplier a routine annual quality audit at the Supplier's premises. The routine quality audit frequency may be increased by the Authority if there is an emergent area of concern in the Supplier's facilities or operations.

23.5. Should the Supplier Sub-contract any of its obligations to a Material Sub-contractor under this Agreement, the Authority shall have the right to audit and inspect such third party. The Supplier shall procure permission for the Authority or its authorised representative during normal business hours no more than once in any twelve (12) months, having given advance notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Agreement that are subcontracted to such Sub-contractor. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested. During a Pandemic the Supplier shall procure permission for the Authority or its authorised representative during normal business hours, having given advance notice of no less than one (1) Business Day, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Agreement that are subcontracted to such Sub-contractor, should the Authority have reasonable grounds for concern regarding the ability of the Supplier to fulfil its obligations hereunder. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested.

23.6. The Supplier shall take appropriate steps to ensure that neither the Supplier nor any Staff is placed in a position where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Agreement. The Supplier will disclose to the Authority full particulars of any such conflict of interest which may arise.

23.7. The Authority reserves the right to terminate this Agreement by notice in writing where there is an actual conflict between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Agreement, provided that such termination may be made only where the conflict concerned has not been remedied by the Supplier within seven (7) days of having received written notice from the Authority requesting such remediation. The actions of the Authority pursuant to this Clause 23.7 shall not prejudice or affect any right of action or remedy which shall have accrued or shall thereafter accrue to the Authority.

23.8. The Supplier shall take all reasonable steps to prevent Fraud by Staff and the Supplier (including its shareholders, members and directors) in connection with the receipt of monies from the Authority. The Supplier shall notify the Authority immediately in writing if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.

23.9. If the Supplier or its Staff commits Fraud in relation to this or any other contract with the Crown (including the Authority) the Authority may: (i) terminate this Agreement and recover from the Supplier the amount of any loss suffered by the Authority resulting from the termination, including the cost reasonably incurred by the Authority of making other arrangements for the supply of the Product and any additional expenditure incurred by the Authority throughout the remainder of the Term; or (ii) recover in full from the Supplier any other loss sustained by the

Authority in consequence of any breach of Clause 23.8.

24. ENVIRONMENTAL CONSIDERATIONS

24.1. The Supplier shall comply in all material respects with applicable environmental Laws and regulations in force from time to time in relation to the Product. Where the provisions of any such legislation are implemented by the use of voluntary agreements or codes of practice, the Supplier shall comply with such agreements or codes of practice as if they were incorporated into Law, subject to those voluntary agreements being cited in the Invitation to Participate in Dialogue. Without prejudice to the generality of the foregoing, the Supplier shall:

24.1.1. comply with all reasonable stipulations of the Authority aimed at minimising the packaging in which the Product is supplied;

24.1.2. promptly provide such data as may reasonably be requested by the Authority from time to time regarding the weight and type of packaging according to material types used in relation to the Product;

24.1.3. comply with all obligations imposed on it in relation to the Product by the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (SI 2007/871) (or any other equivalent legislation giving effect in any part of the European Economic Area to the Packaging and Packaging Waste Directive 94/62/EC);

24.1.4. without prejudice to the Supplier's other obligations under this Agreement, label all Doses of the Product, and the packaging of those Doses, to highlight environmental and safety information as required by applicable UK and EU legislation;

24.1.5. promptly provide all such information regarding the environmental impact of the Product as may reasonably be required by the Authority to permit informed choices by patients and other third parties; and

24.1.6. where the Product is imported into the United Kingdom then for the purposes of the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (SI 2007/871), assume the rolled-up obligations for all the activities performed outside the United Kingdom in relation to the Product and the packaging which is used for the containment, protection, handling, delivery and presentation of the Product in addition to any other obligations it may have pursuant to the said Regulations.

24.2. The Supplier shall meet all reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 24.

25. EQUALITY, NON-DISCRIMINATION AND HUMAN RIGHTS

25.1. The Supplier shall not:

25.1.1. engage in any prohibited conduct as defined in part 2 chapter 2 of the Equality Act 2010 (c.15) (the "**Equality Act**") in relation to any protected characteristic (as defined in section 4 of the Equality Act) where this would contravene any provisions of the Equality Act, including part 3 (goods and services) and part 5 (employment); or

25.1.2. do (or omit to do) anything else that would amount to a contravention of the Equality Act including part 8 (prohibited conduct: ancillary) and chapter 3 part 5 (equality of terms).

25.2. The Supplier shall notify the Authority immediately in writing of any investigation of or proceedings against the Supplier, whether under the Equality Act or any predecessor legislation and shall cooperate fully and promptly with any requests of the person or body conducting such investigation or proceedings, including allowing access to any documents or data required, attending any meetings and providing any information requested.

25.3. Subject to Clause 19, the Supplier shall indemnify the Authority against all costs, claims, charges, demands, liabilities, damages, losses and expenses incurred or suffered by the Authority arising out of or in connection with any investigation conducted or any proceedings brought under any legislation referred to in this Clause 25 due directly or indirectly to any act or omission by the Supplier, its agents, employees or sub-contractors.

25.4. The Supplier shall impose on any Sub-contractors obligations substantially similar to those imposed on the Supplier by this Clause 25.

25.5. In addition to its obligations under this Clause 25 relating to the Equality Act, the Supplier shall:

25.5.1. ensure that it complies with all other current employment legislation and, in particular, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 (SI 2000/1551), the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034), or any other relevant legislation relating to discrimination in the employment of employees. The Supplier shall take all reasonable steps (at its own expense) to ensure that any employees employed in the manufacture or supply of the Product do not unlawfully discriminate within the meaning of this Clause 25.5; and

25.5.2. in the management of its affairs and the development of its equality and diversity policies, the Supplier shall co-operate with the Authority in light of the Authority's obligations to comply with its statutory equality duties whether under part 11 of the Equality Act or otherwise. The Supplier shall take such steps as the Authority considers appropriate to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age.

25.6. The Supplier shall, and shall use reasonable endeavours to ensure that its employees or agents and/or Sub-contractors shall, at all times, act in a way which is compatible with the Convention rights within the meaning of Section 1 of the Human Rights Act 1998 (c.42).

25.7. Subject to Clause 19, the Supplier agrees to indemnify and keep indemnified the Authority against all loss, costs, proceedings or damages whatsoever arising out of or in connection with any breach by the Supplier of its obligations under Clause 25.

26. ENTIRE AGREEMENT

26.1. This Agreement, together with the Invitation to Participate in Dialogue, the Invitation to Submit Final Tenders and the Offer, constitutes the entire understanding of the Parties to the exclusion of all previous agreements, confirmations and understandings, and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Agreement, or the other documents referenced in this Clause 26, provided that nothing in this Agreement shall exclude liability for any fraudulent misrepresentation. Each Party acknowledges that in entering into this Agreement it does not rely on, and shall have no remedies in respect of, any representation or warranty (whether made innocently or negligently) that is not set out in this Agreement or the other documents referenced in this Clause 26.

27. AUTHORISED REPRESENTATIVE

27.1. At the Effective Date the authorised representative of each Party is:

For the Authority: Deputy Director Vaccines and Countermeasures, 10 South Colonnade, Canary Wharf, London E14 5EA

countermeasuressupply@ukhsa.gov.uk

For the Supplier: Redacted Under FOIA Section 40, Personal Information
Seqirus UK Limited, Point, 29 Market Street, Maidenhead, SL6 8AA
Redacted Under FOIA Section 40, Personal Information

Redacted Under FOIA Section 40, Personal Information, Seqirus AG, 4054 Basel – Switzerland
Redacted Under FOIA Section 40, Personal Information
Redacted Under FOIA Section 40, Personal Information

27.2. The authorised representative of a Party may be varied by that Party by notice in writing to the other Party.

28. VARIATION

28.1. Subject to Clauses 27.1, 28.2 and 36.1, should either Party wish to vary this Agreement no such variation shall be binding unless and until it has been agreed in accordance with the Change Control Process in Schedule 10.

28.2. The Authority may, at its sole discretion, from time to time determine that certain minor changes to this Agreement are not required to go through the Change Control Process in Schedule 10 in which case such changes shall be valid and binding once agreed in writing by each Party with reference to this Clause 28.2.

29. RELATIONSHIP BETWEEN THE PARTIES

29.1. Each of the Parties hereto is an independent contractor and nothing contained in this Agreement shall be construed to imply that there is any relationship between the Parties of partnership or of principal/agent or of employer/employee nor are the Parties hereby engaging in a joint venture and accordingly neither of the Parties shall have any right or authority to act on behalf of the other nor to bind the other by agreement or otherwise, unless expressly permitted by the terms of this Agreement.

30. PROHIBITED ACTS

30.1. The Supplier warrants and represents that:

30.1.1. it has not committed any offence under the Bribery Act 2010 (c.23) or done any of the following (referred to hereafter as "**Prohibited Acts**"):

30.1.1.1. offered, given or agreed to give any officer or employee of the Authority any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining of performance of this or any other agreement with the Authority or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority; or

30.1.1.2. in connection with this Agreement paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the Authority; and

30.1.2. it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010 (c.23).

30.2. If the Supplier, its Material Sub-contractors, Direct Sub-contractors, employees or agents (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committedor commits any offence under the Bribery Act 2010 (c.23), with or without the knowledge of the Supplier, in relation to this or any other agreement with the Authority:

30.2.1. the Authority shall be entitled:

30.2.1.1. to terminate this Agreement and recover from the Supplier the amount of any loss resulting from the termination, provided that in the case that any such Prohibited Acts done or being done or such commitment of offence done or being done under the Bribery Act 2010 (c.23) refers to a Material Sub-contractor or Direct Sub-contractor, such right to terminate shall not apply if the Supplier notifies the Authority within five (5) days of receipt of notice of termination that it intends to replace such Material Sub-contractor or Direct Sub-contractor, exercises its reasonable endeavours to agree with the Authority on a plan for the replacement of such Material Sub-contractor or Direct Sub-contractor and pursues such plan, or, in case the Parties have not been able to agree on a plan, pursues activities with diligence, towards replacement of such Material Sub-contractor or Direct Sub-contractor with a new Material Sub-contractor or Direct Sub-contractor, as applicable;

30.2.1.2. to recover from the Supplier the amount or value of any gift, consideration or commission concerned; and

30.2.1.3. to recover from the Supplier any other loss or expense

sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence;

30.2.2. any termination under Clause 30.2.1 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and

30.2.3. notwithstanding Clause 21 (Disputes), any dispute relating to:

30.2.3.1. the interpretation of Clause 30; or

30.2.3.2. the amount or value of any gift, consideration or commission,

shall be determined by the Authority and the decision shall be final and conclusive.

31. ASSIGNMENT, NOVATION AND SUBCONTRACTING

31.1. The Supplier:

31.1.1. shall not, except where Clause 31.1.2 applies, assign or in any other way dispose of the whole or any part of this Agreement without the previous consent in writing of the Authority. The Supplier shall not Sub-contract one or more of the activities listed in Schedule 18 without the prior written consent of the Authority, not to be unreasonably withheld. If with the Authority's consent, as required, the Supplier so Sub-contracts, every act or omission of the Sub-contractor shall for the purposes of this Agreement be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority thereafter as if such act or omission had been committed or omitted by the Supplier itself; and

31.1.2. notwithstanding Clause 31.1.1, may assign to a third party ("**the Assignee**") the right to receive payment of any sums due and owing to the Supplier under this Agreement for which an invoice has been issued or any part thereof (including any interest which the Authority incurs under Clause 14.6). Any assignment under this Clause 31.1.2 shall be subject to:

31.1.2.1. the reduction of any sums in respect of which the Authority exercises its right of recovery under Clause 14.7;

31.1.2.2. all related rights of the Authority in relation to the recovery of sums due but unpaid;

31.1.2.3. the Authority receiving notification of the assignment and the date upon which the assignment becomes effective together with the Assignee's contact information and bank account details to which the Authority shall make payment;

31.1.2.4. the provisions of Clause 14 continuing to apply in all other respects after the assignment which shall not be amended without the prior written approval of the Authority; and

31.1.2.5. payment to the Assignee being full and complete satisfaction of the Authority's obligation to pay the relevant sums in accordance with this Agreement.

31.2. Any authority given by the Authority for the Supplier to Sub-contract any of its obligations hereunder shall not impose any duty on the Authority to enquire as to the competency of any authorised Sub-contractor, and the Supplier shall ensure that any authorised Sub-contractor has the appropriate capability and capacity to perform the relevant obligations and that the obligations carried out by such Sub-contractor are fully in accordance with this Agreement.

31.3. Where the Supplier enters into a Sub-contract in respect of any of its obligations under this Agreement related to the manufacture, supply, delivery or installation of or training in relation to the Products, the Supplier shall include provisions in each such Sub-contract, unless otherwise agreed with the Authority in writing, which:

31.3.1. contain at least equivalent obligations as set out in this Agreement in relation to such manufacture, supply, delivery or installation of or training in relation to the Products to the extent relevant to such Sub-contracting;

31.3.2. contain at least equivalent obligations as set out in this Agreement in respect of confidentiality, information security, data protection, Intellectual Property Rights, compliance with Law and Guidance and record keeping;

31.3.3. in the case of a Sub-contract with a Material Sub-contractor, contain a prohibition on the Material Sub-contractor Sub-contracting, assigning or novating any of its rights or obligations under such Sub-contract without the prior written approval of the Authority (such approval not to be unreasonably withheld or delayed);

31.3.4. in the case of a Sub-contract with a Material Sub-Contractor, require the Supplier or other party receiving goods under the contract to consider and verify invoices under that contract in a timely fashion;

31.3.5. provide that if the Supplier or other party fails to consider and verify an invoice in accordance with Clause 31.3.4, the invoice shall be regarded as valid and undisputed for the purpose of Clause 31.3.6 after a reasonable time has passed;

31.3.6. require the Supplier or other party to pay any undisputed sums which are due from it to the Sub-contractor within a specified period not exceeding thirty (30) days of verifying that the invoice is valid and undisputed;

31.3.7. permit the Supplier to terminate, or procure the termination of, the relevant Sub-contract in the event the Sub-contractor fails to comply in the performance of its Sub-contract with legal obligations in the fields of environmental, social or labour Law, where the Supplier is required to replace such Sub-contractor in accordance with Clause 15.6.3;

31.3.8. permit the Supplier to terminate, or to procure the termination of, the relevant Sub-contract where the Supplier is required to replace such Sub-contractor in accordance with Clause 31.4; and

31.3.9. require the Sub-contractor to include a clause to the same effect as this 31.3 in any Sub-contract which it awards, save that only Material Sub-contractors shall be required to include the provisions set out in Clause 31.3.3 and 31.3.4 in any Sub-contract with Material Sub-contractors which they award.

31.4. Where the Authority considers that the grounds for exclusion under Regulation 57

of the Public Contracts Regulations 2015 (SI 2015/102) apply to any Sub-contractor, then:

31.4.1. if the Authority finds there are compulsory grounds for exclusion, the Supplier shall ensure, or shall procure, that such Sub-contractor is replaced or not appointed; or

31.4.2. if the Authority finds there are non-compulsory grounds for exclusion, the Authority may require the Supplier to ensure, or to procure, that such Sub-contractor is replaced or not appointed and the Supplier shall comply with such a requirement.

31.5. The Authority shall upon written request have the right to review any Sub-contract entered into by the Supplier in respect of the provision of the Products and the Supplier shall provide a certified copy of any Sub-contract within five (5) Business Days of the date of a written request from the Authority. For the avoidance of doubt, the Supplier shall have the right to redact any confidential pricing information in relation to such copies of Sub-contracts.

31.6. The Authority may at any time transfer, assign, novate or otherwise dispose of its rights and obligations under this Agreement or any part of this Agreement:

31.6.1. to any body: (a) that performs any of the functions and/or responsibilities that had previously been performed by the Authority; and/or (b) to whom a material part of the assets or undertaking of the Authority is transferred, including in each case any such body that is: (i) a new body resulting from a re-organisation, consolidation or merger of the Authority and any Contracting Authority; and/or (ii) a private sector body; and/or

31.6.2. to any Contracting Authority.

31.7. Any change in the legal status of the Authority shall not affect the validity of this Agreement.

32. ADDITIONAL SUPPLY CHAIN MATTERS

32.1. The Supplier shall:

32.1.1. subject to Clause 32.3, advertise on Contracts Finder all Sub-contract opportunities arising from or in connection with the manufacture and provision of the Products pursuant to this Agreement above a minimum threshold of twenty five thousand pounds (£25,000) that arise during the Term, provided that such Sub-contract opportunities are with Sub-contractors that would qualify as Material Sub-contractors or Direct Sub-contractors;

32.1.2. within ninety (90) days of awarding a Sub-contract to a Material Sub-contractor or Direct Sub-contractor, update the notice on Contracts Finder with details of the successful Sub-contractor;

32.1.3. monitor the number, type and value of the Sub-contract opportunities placed on Contracts Finder advertised and awarded in its supply chain during the Term;

32.1.4. provide reports on the information at Clause 32.1.3, to the Authority in the

format and frequency as reasonably specified by the Authority; and

32.1.5. promote Contracts Finder to its suppliers and encourage those organisations to register on Contracts Finder.

32.2. Each advert referred to at Clause 32.1.1 shall provide a full and detailed description of the Sub-contract opportunity with each of the mandatory fields being completed on Contracts Finder by the Supplier.

32.3. The obligation at Clause 32.1.1 shall only apply in respect of Sub-contract opportunities arising after the Agreement award date.

32.4. Notwithstanding Clause 32.1, the Authority may by giving its prior written approval, agree that a Sub-contract opportunity with a Sub-contractor that would qualify as a Material Sub-contractor or a Direct Sub-contractor is not required to be advertised on Contracts Finder.

32.5. In addition to any other management information requirements set out in this Agreement, the Supplier agrees and acknowledges that it shall, at no charge, provide timely, full, accurate and complete reports ("**SME Management Information Reports**") to the Authority which incorporate the data described in the Supply Chain Transparency Information Template.

32.6. The SME Management Information Reports shall be provided in the correct format as required by the Supply Chain Transparency Information Template and any guidance issued by the Authority from time to time. The Supplier shall use the Supply Chain Transparency Information Template which may be changed from time to time (including the data required and/or format) by the Authority by issuing a replacement version. The Authority shall give at least thirty (30) days' notice in writing of any such change and shall specify the date from which it must be used.

32.7. The Supplier further agrees and acknowledges that it may not make any amendment to the current Supply Chain Transparency Information Template without the prior written approval of the Authority.

33. MODERN SLAVERY

33.1. To the extent not already required by any other provisions of this Agreement, the Supplier shall comply with the requirements of this Clause 33.

33.2. The Supplier shall, and shall procure that each of its Sub-contractors shall, comply with:

33.2.1. the Modern Slavery Act 2015 (c.30) ("**Slavery Act**"); and

33.2.2. the Authority's anti-slavery policy as provided to the Supplier by the Authority from time to time ("**Anti-Slavery Policy**").

33.3. The Supplier shall:

33.3.1. implement due diligence procedures for its Sub-contractors and other participants in its supply chains to ensure that there is no slavery or human trafficking in any part of its supply chains;

33.3.2. make reasonable enquiries to ensure that its Staff and Sub-contractors have

not been convicted of slavery or human trafficking offences anywhere around the world;

33.3.3. respond promptly to all slavery and trafficking due diligence questionnaires issued to it by the Authority from time to time and shall ensure that its responses to all such questionnaires are complete and accurate;

33.3.4. prepare and deliver annually to the Authority a report which is compliant with section 54 of the Slavery Act, and complete and provide annually to the Authority, a copy of Supplier's completed Modern Slavery Assessment Tool using the Modern Slavery Assessment Tool available on the Cabinet Office website at: https://supplierregistration.cabinetoffice.gov.uk/msat, which website address may be updated from time to time;

33.3.5. implement a system of training for its employees to ensure compliance with the Slavery Act;

33.3.6. have and maintain throughout the Term its own policies and procedures to ensure its compliance with the Slavery Act and ensure that any Sub-contracts contain anti-slavery provisions consistent with the Supplier's obligations under this Clause 33;

33.3.7. not require any Staff or the employees of any Sub-contractors to lodge deposits or identity papers with their employer and ensure that such employees shall be free to leave their employer after reasonable notice;

33.3.8. not use, or allow its Staff or Sub-contractors to use, physical abuse or discipline, the threat of physical abuse, sexual or other harassment and verbal abuse or other forms of intimidation of its Staff or Sub-contractors; and

33.3.9. not use, or allow its Sub-contractors to use, forced, bonded or involuntary prison labour or child or slave labour.

33.4. The Supplier undertakes on an ongoing basis that:

33.4.1. it conducts its business in a manner consistent with all applicable Laws including the Slavery Act and all analogous legislation in place in any part of the world in which its supply chain operates;

33.4.2. its response to all slavery and trafficking due diligence questionnaires issued to it by the Authority from time to time are complete and accurate; and

33.4.3. neither the Supplier nor any of its Sub-contractors, nor any of its or their Staff:

33.4.3.1. has been convicted of any offence involving slavery or trafficking anywhere around the world; or

33.4.3.2. has been, or is currently, the subject of any investigation, inquiry or enforcement proceedings by any governmental, administrative or regulatory body relating to any offence committed regarding slavery or trafficking anywhere around the world,

not already notified to the Authority in writing in accordance with Clause 33.5.

33.5. The Supplier shall notify the Authority and the Modern Slavery Helpline and relevant national or local law enforcement agencies as soon as it becomes aware of:

33.5.1. any breach of the Anti-Slavery Policy; or

33.5.2. any actual slavery or trafficking, forced labour, child labour, involuntary prison labour or labour rights abuses in its supply chain.

33.6. If the Supplier notifies the Authority pursuant to Clause 33.5 , it shall respond promptly to the Authority's enquiries, co-operate with any investigation, and allow the Authority to audit any books, records and/or any other relevant documentation in accordance with the Agreement.

33.7. If the Supplier or the Authority identifies any occurrence of modern slavery connected to this Agreement, the Supplier shall comply with any request of the Authority to submit a remedial action plan which follows the form set out in Annex D of the guidance published with Procurement Policy Note 02/23 - Tackling Modern Slavery in Government Supply Chains.

33.8. If the Supplier discovers or suspects any slavery, trafficking, forced labour, child labour, involuntary prison labour or labour rights abuses by it or its Sub-contractors, the Supplier shall report such discoveries or suspicions to:

33.8.1. for victims or potential victims in the United Kingdom, the Modern Slavery Helpline;

33.8.2. for victims or potential victims in the European Union, that nations Modern Slavery Hotline (EU States);

33.8.3. for victims or potential victims not in the United Kingdom or European Union, any relevant national reporting mechanism; or

33.8.4. where the state in which the victims or potential victims are located does not have a national reporting mechanism, the Modern Slavery Helpline.

33.9. If the Authority reasonably believes there is a risk of modern slavery or trafficking offences in the supply chain, allow the Authority or an independent third party to carry out an unannounced or semi-announced inspection of any facilities used in the manufacture, storage and distribution of the Products and speak directly to any Supplier employee in a confidential manner and in the native language of such Supplier employee in respect of workforce conditions, working or employment practices.

33.10. If the Supplier is in breach of Clause 33.3 or the undertaking at Clause 33.4, in addition to its other rights and remedies provided under this Agreement, the Authority may:

33.10.1. by written notice require the Supplier to remove from performance of any contract or framework agreement with the Authority (including this Agreement) any Sub-contractor, Staff or other persons associated with it whose acts or omissions have caused the breach; or

33.10.2. terminate this Agreement by providing written notice to the Supplier.

34. SOCIAL VALUE

34.1. The Supplier shall meet the social value commitments set out in Schedule 19 ("**Social Value Commitments**"). The Supplier shall provide Quarterly reports (the first such report falling due three (3) months following the Effective Date) confirming its progress as against its Social Value Commitments. Prior to submitting the first such report, the Supplier shall agree the precise format for such reports with the Authority. As part of agreeing such format, the Supplier shall agree to include any relevant information in such format as may reasonably be requested by the Authority.

34.2. Without prejudice to the Authority's other rights and remedies under this Agreement:

34.2.1. to the extent that the Supplier fails to progress its Social Value Commitments in accordance with the stated timescales set out in Clause 34.1 and/or Schedule 19, it shall within a reasonable period following a written request from the Authority agree an action plan with the Authority to remedy such failure (with both Parties acting reasonably in agreeing such action plan);

34.2.2. a failure by the Supplier to (i) agree such an action plan with the Authority in a reasonable period (to be determined by the Authority at its sole discretion, acting reasonably); or (ii) to remedy such failure to progress its Social Value Commitments in accordance with the agreed action plan shall be escalated by the Authority to the Chief Executive Officer (or equivalent) of the Supplier; and

34.2.3. once escalated to the Chief Executive Officer (or equivalent) of the Supplier, such individual shall write to the Authority within ten (10) Business Days of such escalation confirming the steps (with associated timescales) that the Supplier will be taking to remedy such failure to progress its Social Value Commitments by the earliest date reasonably possible. The Supplier will then remedy such failure by taking such steps by such timescales and by taking any other reasonable additional steps that may become necessary to ensure that such failure to progress its Social Value Commitments is remedied by the earliest date reasonably possible.

35. WAIVER

35.1. Failure by either Party to exercise an option or right conferred by this Agreement shall not of itself constitute a waiver of such option or right.

35.2. The failure by the Authority or the Supplier to insist upon the strict performance of any provision, term or condition of this Agreement or to exercise any right or remedy consequent upon the breach thereof shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.

36. NOTICE

36.1. Any notice to be given under this Agreement by:

36.1.1. the Supplier to the Authority shall be sent for the attention of the Commercial Lead Pandemic Influenza Preparedness Programme of the Authority and the address for notices or confirmations sent by post shall be: Vaccines and

Medical Countermeasures Team, UK Health Security Agency, 10 South Colonnade, Canary Wharf, London E14 5EA, and the address for notices or confirmations sent by email shall be: countermeasuressupply@ukhsa.gov.uk; and

36.1.2. the Authority to the Supplier shall be sent for the attention of the authorised representative of the Supplier as notified to the Authority in accordance with Clause 27.1 address for notices or confirmations sent by post shall be: Seqirus UK Limited, Point, 29 Market Street, Maidenhead, Berkshire SL6 8AA, and the address for notices or confirmations sent by email shall be Redacted Under FOIA Section 40, Personal Information

The above contact details of a Party may be varied by that Party by notice in writing to the other Party.

36.2. A notice shall be treated as having been received:

36.2.1. if delivered by hand within normal business hours when so delivered, or, if delivered by hand outside normal business hours, at the next start of normal business hours; or

36.2.2. if sent by first class recorded delivery mail on a normal Business Day, at 9.00 am on the second Business Day subsequent to the day of posting, or, if the notice was not posted on a Business Day, at 9.00 am on the second Business Day subsequent to the day of posting; or

36.2.3. if sent by email, if sent within normal business hours when so sent, or, if sent outside normal business hours, at the next start of normal business hours, provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient to inform the recipient that the email has been sent.

37. SEVERANCE

37.1. Any provision of this Agreement which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions hereof and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

38. MISREPRESENTATION

38.1. The Supplier acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Agreement and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the Authority for any misrepresentation (whether made carelessly or not) or for breach of any warranty unless the representation relied upon is set out in this Agreement or unless such representation was made fraudulently.

39. COSTS AND EXPENSES

39.1. Each Party shall bear its own expenses in relation to the preparation and execution of this Agreement including all costs legal fees and other expenses so incurred.

40. REMEDIES

40.1. The rights and remedies provided in this Agreement are cumulative and not exclusive of any rights or remedies provided by general law, or by any other contract or document. In this provision, right includes any power, privilege, remedy, or proprietary or security interest.

41. THIRD PARTY RIGHTS

41.1. The Supplier acknowledges that the Authority has entered into this Agreement in the context of the exercise of performance of the duties of the Secretary of State for Health and Social Care under the National Health Service Act 2006 (c.41) as amended by the Health and Social Care Act 2012 (c.7), and on behalf of the Welsh Ministers under the National Health Service (Wales) Act 2006 (c.42), the Scottish Ministers under the National Health Service (Scotland) Act 1978 (c.29) and the Ministry under the Health and Personal Social Services (Northern Ireland) Order 1972 S.I 1972/1265 (N.I.14). Accordingly, for the purposes of assessing the extent of any liability of the Supplier to the Authority, any relevant loss or damage or any liability incurred by any Administering Entity and/or any Devolved Administration shall be deemed to be loss or damage or liability incurred by the Authority.

41.2. Any Administering Entity and/or any Devolved Administration may enforce any term of this Agreement which confers a benefit on it. Subject to the foregoing, a person who is not a Party to this Agreement shall have no right to enforce any terms of it which confer a benefit on him. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Agreement.

42. GOVERNING LAW AND JURISDICTION

42.1. This Agreement, and any dispute or claim arising out of or in connection with it or its subject matter, shall be governed by, and construed in accordance with, the Laws of England and Wales.

42.2. Subject to Clause 21, the Parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter.

Signed by the authorised representative of THE AUTHORITY

Signed by the authorised representative of THE SUPPLIER

SCHEDULE 1

Preparatory Activities

Following and including the Effective Date, the Supplier will commence the following preparatory activities:

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 2

Specification

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 3

Contract Price

Pandemic Preparedness Fees

Subject to Clause 14.3 and the paragraph immediately below relating to Service Point deductions, **Redacted Under FOIA Section 43(2), Commercial Interests**

Any Service Point deductions due in accordance with Schedule 6 (Key Performance Indicators) will be applied to the Pandemic Preparedness Fee in the first Quarter ending after the Contract Year in which they accrue and so the Pandemic Preparedness Fee will not be paid for that Quarter until: (i) after the Contract Review Meeting at which the Supplier and the Authority review the Performance Monitoring Report for the relevant Project Year (as defined in Schedule 6); or (ii) in the case that no such Contract Review Meeting has been held within thirty (30) days of the end of such Quarter for reasons that are not attributable to the Supplier, forty-five (45) days have passed after the end of such Quarter.

Fees for supply of Products

Number of Doses ordered in respect of the relevant Pandemic		**Fees for supply of each Dose of Product where the total number of Doses ordered for the relevant Pandemic falls within the range**
Range minimum (in million Doses)	**Range maximum (in million Doses)**	**Fee per Dose (£) excluding VAT fixed for the duration of this Agreement**
Redacted Under FOIA Section 43(2), Commercial Interests	**Redacted Under FOIA Section 43(2), Commercial Interests**	**Redacted Under FOIA Section 43(2), Commercial Interests**
Redacted Under FOIA Section 43(2), Commercial Interests	**Redacted Under FOIA Section 43(2), Commercial Interests**	**Redacted Under FOIA Section 43(2), Commercial Interests**
Redacted Under FOIA Section 43(2), Commercial Interests	**Redacted Under FOIA Section 43(2), Commercial Interests**	**Redacted Under FOIA Section 43(2), Commercial Interests**

SCHEDULE 4

Conditions that apply should the Authority require the Supplier to switch to manufacture of the Product in advance of a Declaration of a Pandemic

1 Following the escalation of the World Health Organization's phases of alert in respect of an influenza Pandemic to Alert Stage B (Preparation Stage) under the Revised WHO Classification System, the Supplier shall, at the written request of the Authority, meet with the Authority within two Business Days of such request (or such other time as may be agreed with the Authority) to discuss the appropriate time to switch its Manufacturing Facilities to manufacture the Product.

2 Subject always to the Supplier fulfilling its obligations under Clause 3.2 of this Agreement, the Supplier shall keep any decision made pursuant to paragraph 1 above not to switch its Manufacturing Facilities to manufacture the Product under review. The Supplier shall any time during Alert Stage B (Preparation Stage) under the Revised WHO Classification System of the World Health Organization's phases of alert following the Authority's written request meet with the Authority within two Business Days of such request (or such other time as may be agreed with the Authority) to review such decision.

3 A number of variables outside of the Supplier's control may impact its ability to supply Pandemic vaccine at Alert Stage B (Preparation Stage) under the Revised WHO Classification System:

- Existing contractual commitments to supply seasonal influenza vaccine;
- Availability of a suitable Seed Virus; and
- Regulatory support to expedite product approval.

4 The Supplier will only change from seasonal to Pandemic vaccine production when a firm Order has been received.

5 A minimum purchase Order Volume Redacted Under FOIA Section 43(2), Commercial Interests will be required.

6 Delivery timelines and cancellation provisions as included in this Agreement under Pandemic Phase under the Revised WHO Classification System will not apply:

6.1 The Supplier will use Commercially Reasonable Endeavours to manufacture the Pandemic vaccine; and

6.2 Orders for which manufacturing has commenced are cancellable only at a Risk-Sharing Fee payment of Redacted Under FOIA Section 43(2), Commercial Interests of the fee otherwise due for the Doses cancelled.

7 The Doses produced under Alert Stage B (Preparation Stage) under the Revised WHO Classification System are a reduction of total capacity reserved under the Agreement available following a declaration of Pandemic Phase under the Revised WHO Classification System for the same or closely related Pandemic strain.

8 In case the Supplier is producing seasonal influenza vaccine at the time Alert Stage B (Preparation Stage) under the Revised WHO Classification System is declared, prior to

changing from seasonal to Pandemic vaccine production, the Supplier and the Authority will discuss all risks and compensations as a result of the change. The change-over will only take place when mutual agreement has been obtained between the Parties on these matters.

9 After consultation with WHO, Regulatory Agencies, the Authority and other interested First Wave Purchasers, the Supplier will select the most appropriate Seed Virus to be used in Alert Stage B (Preparation Stage) under the Revised WHO Classification System vaccine production and will use the same Seed Virus for all First Wave Purchasers at any given time in Alert Stage B (Preparation Stage) under the Revised WHO Classification System (as using multiple Seed Viruses would cause prohibitive inefficiencies and complexities). If a new Seed Virus becomes available and is needed for immunogenicity reasons, the Supplier will change to that Seed Virus if WHO, Regulatory Agencies and all First Wave Purchasers agree to it.

10 Quantities produced under different seeds cumulatively apply to the Ordered Alert Stage B (Preparation Stage) under the Revised WHO Classification System Volume during the respective Pandemic event.

11 If WHO endorses and makes available a new or different seed virus in WHO Alert Stage B (Preparation Stage) under the Revised WHO Classification System that becomes available following the start of the Supplier's commercial scale production in Alert Stage B (Preparation Stage) under the Revised WHO Classification System, then the Supplier alone may decide whether or not to switch to that seed strain for further vaccine production in Alert Stage B (Preparation Stage) under the Revised WHO Classification System or Pandemic Phase under the Revised WHO Classification System.

12 Before the Supplier starts formulation of product, the release process and criteria have to be agreed by the Parties:

12.1 Reagents are available and satisfactory for release; or

12.2 To use Alternative Release Methodology for release.

13 If the Authority requests the Supplier to commence formulation (blend) production in advance of a suitable calibrating assay reagent being available, the Parties shall first agree the financial risk being taken by the Authority, as these costs would need to be paid for by the Authority whether or not the product would ultimately be successfully released.

14 The Licensing Authority Pandemic Preparedness Vaccine registration requires a Pandemic Phase under the WHO Classification System to be declared prior to Variation of the Marketing Authorisation to a Pandemic Specific Vaccine. Under Alert Stage B (Preparation Stage) under the WHO Classification System alternative regulatory approval routes could be discussed and agreed with the Licensing Authority. A suitable route will need to be agreed between the Supplier and the Authority before the Supplier initiates production and the Supplier will use Commercially Reasonable Endeavours to determine such regulatory pathway. Potential solutions include:

14.1 Negotiate using the Pandemic Preparedness Vaccine file with the Licensing Authority; and

14.2 File strain-change variation with the Licensing Authority.

15 Should the Supplier not have switched its Manufacturing Facilities to manufacture the

Product during Alert Stage B (Preparation Stage) under the Revised WHO Classification System of the World Health Organization's phases of alert, the Supplier shall commence the preparation of the Manufacturing Facilities for the manufacture of the Product immediately upon the Declaration of a Pandemic in accordance with Clause 3.3.2

SCHEDULE 5

Delivery schedule

1 This Schedule 5 sets out how, following the placing of an Order, the Delivery Schedule shall be calculated. In this Schedule 5:

"**Actual Yield**" means the **Redacted Under FOIA Section 43(2), Commercial Interests**;

"**Initial Delivery Date**" means the later of: **Redacted Under FOIA Section 43(2), Commercial Interests**;

"**Weekly Supply**" means the Reserved Capacity multiplied by the Yield Factor;

"**Yield Assumption**" has the meaning set out below; and

"**Yield Factor**" means the Actual Yield divided by the Yield Assumption.

2 The Supplier shall commence delivery of the Product to the Authority no later than the Initial Delivery Date.

3 The Supplier shall ensure that at the end of each week following the Initial Delivery Date until deliveries under the relevant Order have been completed, the cumulative volume of Product delivered to the Authority is no less than the cumulative total of the Weekly Supply for each week. By way of example only, where the Weekly Supply is, at **Redacted Under FOIA Section 43(2), Commercial Interests** the end of the fourth week following the Initial Delivery Date, the total volume of Product delivered to the Authority shall be a minimum of **Redacted Under FOIA Section 43(2), Commercial Interests**.

4 The Supplier shall notify the Authority in writing in advance with full details of the volume of Product to be delivered to the Authority and the dates for delivery of each shipment of Product to the Authority in accordance with the above delivery obligations. Such notification shall be in accordance with the reporting obligations set out in Clause 10.

5 Without prejudice to the above obligations, the Supplier shall ensure that the Delivery Schedule reflects the earliest possible date by which the Supplier anticipates that it will be in a position to deliver the relevant Doses of Product to the Authority.

6 "**Yield Assumption**" **Redacted Under FOIA Section 43(2), Commercial Interests**

SCHEDULE 6

Key Performance Indicators

1. Purpose of this Schedule

1.1 This Schedule 6 sets out the performance indicators which the Supplier is expected to achieve in the delivery of the Product and preparedness in the Preparedness Phase and otherwise in performing its obligations under this Agreement.

1.2 The Supplier shall, at all times, deliver the Product and preparedness in the Preparedness Phase and perform its obligations under this Agreement in such a manner that the KPIs are consistently achieved.

1.3 The Supplier shall monitor its performance against the KPIs and shall send the Authority a report detailing the level of service which was achieved in accordance with the provisions of Part B of this Schedule 6.

1.4 Where any of the KPIs are not achieved by the Supplier, the remedies set out in Part C of this Schedule 6 shall be available to the Authority.

1.5 In this Schedule 6:

"**Key Performance Indicator" "KPI"** are the key performance indicators set out in Part A1 and Part A2 of this Schedule 6;

"**Performance Monitoring Report**" means the reports to be provided by the Supplier to the Authority in accordance with paragraph 2.1 of this Schedule 6 containing the information set out in paragraph 2.2 of this Schedule 6;

"**Project Year**" is the period of twelve (12) months from 1 July of one year to the 30 June of the following year save only for the first year of this Agreement where the period shall be ten (10) months starting from the Effective Date to the 30 June of the following year;

"**Reporting Period**" is the period set out in paragraph 2.1 of this Schedule 6;

"**Service Credit"** means the sum payable, if any, by the Supplier to the Authority in respect of the Service Points accrued in the respective Preparedness Phase or Pandemic that the KPIs apply to. For the avoidance of doubt, the sum of any Service Credits shall be calculated by multiplying the value of the accrued Service Points by the number of accrued Service Points;

"**Service Points**" means the points that accrue for failure by the Supplier to meet the Key Performance Indicators as set out in this Schedule 6, the value of each being **Redacted Under FOIA Section 43(2), Commercial Interests** multiplied by the total fees for the supply of vaccine (in GBP) paid or payable in respect of the Product ordered by the Authority in the respective Preparedness Phase or Pandemic during which the Service Points accrue. The value of Service Points relating to KPIs applicable to the Preparedness Phase shall be **Redacted Under FOIA Section 43(2), Commercial Interests** multiplied by annual Pandemic Preparedness Fee paid and

payable in respect of the year in which the Service Points accrue; and

"**week**" refers to a period of seven (7) days ending at midnight on a Sunday.

PART A1 – KEY PERFORMANCE INDICATORS for preparedness in the Preparedness Phase

1.6 Key Principles:

1.6.1 Performance measures are defined for each KPI which if not met will result in the Authority accruing Service Points.

1.6.2 Once the preparedness in the Preparedness Phase has been completed in any Project Year of the Agreement, the Service Credits applicable to the Preparedness Phase will be calculated and applied as part of Reconciliation.

1.6.3 No Service Points will accrue where KPI failure is due to an agreed exclusion in the Agreement or to the extent that such KPI failure arises as a direct result of an event of Force Majeure.

1.7 The following KPIs (and corresponding Service Points) shall apply annually during the Preparedness Phase:

1.8 KPI 1: Planning and preparation including supply chain and stockpiles.

The Supplier will:

1. Maintain and provide to the Authority an operational risks and issues log, which should include dates of issues logged, steps to mitigate risks, outcomes of risks/issues/mitigations;

2. Maintain and provide to the Authority a list of critical materials and their shelf life;

3. Provide a RAG rating for each critical material and maintain a preparedness dashboard to present at Quarterly meetings with the Authority; and

4. Provide to the Authority and maintain a delivery schedule of stockpiled components including lead times of critical materials required for stockpiling. Identify and provide to the Authority, and update as required, details of components that have an associated risk in terms of operational manufacture and supply.

Redacted Under FOIA Section 43(2), Commercial Interests shall accrue for each element not provided to the Authority in a timely manner.

KPI 2: UK Manufacturing, including fill finish

The Supplier will remain on track in meeting UK Manufacturing Capability within 30 months of the Effective Date and will be measured by actual monthly progress against its original plan submitted to achieve this. Such monthly progress shall be set out in the Quarterly Performance Monitoring Report broken down for each month of that Quarter.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points accrue on the first full month that this KPI is not met (i.e. following the first month of delay in such plans) increasing by an additional **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points for any subsequent months of continued delay in such plans meaning this KPI is not met.

KPI 3: Steps towards implementing innovation/diversification

The Supplier will:

Accurately report on a quarterly basis (such report being delivered to the Authority within five (5) Business Days of the end of each Quarter) on the progress of its Program of research and development in new and/or improved vaccine production methods (diversification) and on potential changes to the Program and the general reasons therefor.

For the purposes of this KPI3, "**Program**" shall include the following ongoing research and development programs (and any equivalent programs performed by the Supplier):

1. **Redacted Under FOIA Section 43(2), Commercial Interests**

2. **Redacted Under FOIA Section 43(2), Commercial Interests**

Redacted Under FOIA Section 43(2), Commercial Interests Service Points shall accrue in relation to each material element of the report which is inaccurate.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points shall accrue in relation to each report which is not delivered to the Authority on time.

KPI 4: Business Continuity and Resilience Planning

The Supplier will:

1. Test its Business Continuity Plan on an annual basis and conduct a minimum of **Redacted Under FOIA Section 43(2), Commercial Interests** business continuity audits per Project Year;

2. Share with the Authority at each Contract Review Meeting the summary of the latest business continuity audit report;

3. Share with the Authority within five (5) Business Days of the end of each Quarter summaries of the business continuity test and audit reports and any improvement plans completed in the most recent Quarter;

4. Provide updates to the Authority annually on its Business Continuity Plan; and

5. To the extent requested by the Authority, facilitate an annual visit by the Authority of any premises and facilities used in the performance of the Supplier's obligations.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points shall accrue for each element not performed in accordance with the above.

KPI 5: Overview of the Supplier's end-to-end supply chain

The Supplier will:

1. Direct Sub-contractor performance: provide to the Authority an annual summary within five (5) Business Days of the 30th June each Project Year of a report regarding audits of Direct Sub-contractor distributors and Direct Sub-contractors' warehouses and an overview of remediations requested by the Supplier and carried out.

2. Supply Chain Resilience: provide an annual update within five (5) Business Days of the 30th June each Project Year of the Supply Chain Risk Reduction Plan, and a report on progress according to such plan.

In this KPI5, "**Supply Chain Resilience**" means the ability to withstand and recover from an incident, and "**Supply Chain Risk Reduction Plan**" means the Supplier's annual report on risks associated with its current supply chain for the Product and planned mitigation of such risks.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points shall accrue for each element not provided to the Authority within the timeframes specified above.

PART A2 – KEY PERFORMANCE INDICATORS (as applicable for each Pandemic separately during the Term)

1.9 Key Principles:

1.9.1 Performance measures are defined for each KPI which if not met will result in the Authority accruing Service Points.

1.9.2 Once all deliveries of Product have been made in respect of a Pandemic, the Service Credit will be calculated and applied as part of Reconciliation.

1.9.3 No Service Points will accrue where KPI failure is due to an agreed exclusion in the Agreement or to the extent that such KPI failure arises as a direct result of an event of Force Majeure.

1.9.4 The Delivery Schedule against which these KPIs will be measured is defined and calculated as detailed in Schedule 5 for each respective Pandemic.

1.9.5 The maximum aggregate sum payable by the Supplier for failure to meet KPIs in any Contract Year will not exceed the aggregate of: **Redacted Under FOIA Section 43(2), Commercial Interests**.

1.10 The following KPIs (and corresponding Service Points) shall apply in respect of each Order placed by the Authority during each Pandemic:

KPI 1: Start date for commencement of delivery of Product

The first consignment of the Product shall be delivered to the Authority by the Initial Delivery Date as defined in Schedule 5.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points shall accrue for each week of delay in delivery of the first consignment of the Product, and a pro-rated number of Service Points shall accrue in respect of each day of delay where delivery is completed during a week.

KPI 2: Delivery of an aggregate Product volume in accordance with plans

The aggregate volume of Product delivered by the end of a week shall be at least **Redacted Under FOIA Section 43(2), Commercial Interests** of the Volume which the Supplier is obliged to deliver on or before that date under the Delivery Schedule.

This KPI will not apply to the extent that deliveries of the Product in the relevant week are affected by:

(i) the Supplier suffering a Batch failure in relation to the Product as a result of the potency measure being outside the Specification;

(ii) a specific Batch of Product having a lower potency profile than anticipated by the Supplier resulting in lower yield for that Batch as compared with the Actual Yield (as defined in Schedule 5); and/or

(iii) the OMCL, having tested samples from a specific Batch of Product, requiring additional samples of that Batch to be tested, causing delays in release of vaccine where the Product is then released following such testing without further action being required by the OMCL of the Supplier,

provided that the Supplier shall only be entitled to utilise the exemption under (i) or (ii) above on one occasion of Batch failure per Order.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points shall accrue on the first occasion that this KPI is not met at the end of any relevant week, increasing to **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points on any subsequent occasion when this KPI is not met at the end of any relevant week.

KPI 3: Product is rejected following delivery

No more than **Redacted Under FOIA Section 43(2), Commercial Interests** of Doses of Product delivered to or collected by the Authority or the Authorised Agent each calendar month shall entitle the Authority to exercise its right to reject Product in accordance with Clause 8.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points will accrue on the first occasion in a calendar month in which the Rejected Product total exceeds **Redacted Under FOIA Section 43(2), Commercial Interests** of the Doses delivered during that month.

On each subsequent occasion that the monthly Rejected Product exceeds **Redacted Under FOIA Section 43(2), Commercial Interests** of the Doses

delivered during that month, an additional **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points shall accrue.

In the event that no Product Doses are rejected by the Authority in a calendar month, and the Supplier has delivered at least **Redacted Under FOIA Section 43(2), Commercial Interests** of the scheduled Doses in the Delivery Schedule in that month, the Supplier shall earn back **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points where there has been previous accrual of Service Points by the Authority under this KPI 3.

KPI 4: Lead time to ship Product with appropriate labelling and leaflets

The Authority acknowledges that the Supplier may be authorised by the Licensing Authority to label Product prior to full approval for such labelling. Should the Supplier receive such authorisation and the written consent of the Authority, the Supplier shall manufacture and supply the Product in accordance with such authorisation prior to full approval for the labelling.

The Supplier shall ship the manufactured Product from its Manufacturing Facility, together with the appropriate final UK labelling and leaflets, within five (5) weeks of final approval by the Licensing Authority of the relevant Product labelling and patient information leaflets.

This KPI 4 is only applicable where manufacturing is commenced by the Supplier with the written consent of the Authority in advance of the Product obtaining final approval of the labelling and leaflets by the Licensing Authority.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points shall accrue where the time taken by the Supplier to ship the manufactured Product with appropriate labelling and leaflets exceeds five (5) weeks.

Where the time to ship the manufactured Product with appropriate labelling and leaflets exceeds seven (7) weeks, an additional **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points shall accrue.

KPI 5: Accuracy of weekly reports

The Supplier shall deliver the weekly reports to the Authority as required by Clause 10.5 of this Agreement on time, and the information contained in such weekly reports supplied by the Supplier to the Authority shall be one hundred percent (100%) accurate regarding all material aspects.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points shall accrue in relation to each material element of the report which is inaccurate.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points shall accrue in relation to each report which is not delivered to the Authority on time.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points shall accrue in relation to each report which is delivered to the

Authority more than five (5) Business Days late.

In the event that the Authority accrues more than **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points under this KPI 5 in a rolling four (4) week period, all subsequent failures under this KPI 5 shall increase from **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points.

1.11 In the event of any changes to the Delivery Schedule under Clause 5.11, or as otherwise agreed by the Parties in writing (whether under Clause 9.4 or otherwise), the above KPIs (and corresponding Service Points) shall apply in full to the Delivery Schedule as amended.

PART B – MONITORING AND REPORTING

2. KPI reports

2.1 The Supplier shall provide a Performance Monitoring Report to the Authority within two (2) Business Days of the end of each week during a Pandemic following the Authority placing an Order and Quarterly at all other times, and "**Reporting Period**" shall mean each week or Quarter (as applicable).

2.2 The Performance Monitoring Report shall contain, as a minimum, the following information in respect of the Reporting Period:

2.2.1 the KPI monitoring which has been performed with a summary of any KPI issues identified by such monitoring;

2.2.2 for each KPI, the actual performance achieved over the Reporting Period broken down to cover each calendar month in that Quarter, and that achieved over the previous three (3) Reporting Periods;

2.2.3 a summary list of all failures to meet KPIs that occurred during the Reporting Period broken down to cover all failures for each calendar month in that Quarter, together with details of such failures;

2.2.4 which KPI failures remain outstanding and progress in resolving them;

2.2.5 for any repeat failures, actions taken to resolve the underlying cause and prevent recurrence;

2.2.6 details of the Service Points which have accrued as a result of any KPI failures, and any earnback Service Points within the Reporting Period, indicating the failures to which the Service Points relate;

2.2.7 a rolling total of the number of KPI failures that have occurred and the amount of Service Points that have been incurred by the Supplier over the past twelve (12) Reporting Periods;

2.2.8 relevant particulars of any aspects of the performance by the Supplier which fail to meet the requirements of the Agreement; and

2.2.9 such other details as the Authority may reasonably require from time to time.

2.3 The Contract Review Meetings will be the forum for the review by the Supplier and the Authority of the Performance Monitoring Reports. The Authority shall be entitled to raise any additional questions and/or request any further information regarding any KPI failure.

2.4 The Supplier shall provide to the Authority such supporting documentation as the Authority may reasonably require in order to verify the level of the performance by the Supplier and the calculations of the amount of Service Points for any specified period.

PART C – REMEDIES FOR KPI FAILURE

3. Failure to achieve KPIs

3.1 Where the Supplier fails to meet one or more KPIs, the Authority shall be entitled to the remedies set out in this Part C. Where any Service Credits are due to be paid to the Authority, the Authority may, by written notice to the Supplier at any time following such Service Credits falling due, waive its right to receive the relevant Service Credits, in which event: (i) the Authority shall repay any Service Credits received (or in the case of Service Credits applied as a credit to invoices, pay the sum of any applicable credit) in respect of the relevant failure; and (ii) following such payment, the Authority shall then be entitled to pursue other financial remedies under this Agreement for the failure which has given rise to the right to receive the Service Credits concerned. For the avoidance of doubt, this paragraph 3.1 shall have no impact on the availability of any non-financial remedy under this Agreement. The intent of the Parties under this paragraph 3.1 is to avoid any double recovery by the Authority in respect of a single loss.

3.2 Where a failure to achieve a KPI is repeated in two (2) or more consecutive measurement periods, there will be an appropriate increase in the value of the remedy above for specific KPIs.

3.3 Where a specific failure by the Supplier causes two (2) or more KPIs not to be achieved, the remedies for each such KPI failure shall be available to the Authority.

3.4 The Parties agree that the remedies in this Part C are a reasonable basis of compensating the Authority for the relevant failure by the Supplier to achieve the relevant KPI.

4. Service Credits

4.1 Where failure to achieve KPIs results in Service Points, the Authority shall be entitled to convert such Service Points into Service Credits once all deliveries have been made and payment or credit will then be made to the Authority for the value of the Service Credit as part of the Reconciliation.

5. Earnback mechanism

5.1 The Supplier shall be entitled to earn back any Service Points under this Part C where the Supplier demonstrates a material improvement in its performance such that the relevant KPIs are achieved in subsequent weeks, as follows:

5.1.1 Where no Service Points are accrued in a period of six (6) consecutive weeks during a Pandemic during the Term, the Supplier shall be entitled to earn back any Service Points accrued in respect of the preceding three (3) week period if such period also falls during a Pandemic. For the avoidance of doubt, this earnback mechanism shall not apply to Part A2 KPI 1.

5.1.2 As provided for in respect of Part A2 KPI 3 in paragraph 1.10.

5.2 Worked examples of KPIs, Service Points and Service Credits are shown in Annex A.

6. Escalation

6.1 Where the Supplier:

6.1.1 **Redacted Under FOIA Section 43(2), Commercial Interests**

6.1.2 **Redacted Under FOIA Section 43(2), Commercial Interests** or

6.1.3 **Redacted Under FOIA Section 43(2), Commercial Interests**; or

6.1.4 **Redacted Under FOIA Section 43(2), Commercial Interests**; or

6.1.5 **Redacted Under FOIA Section 43(2), Commercial Interests**,

the Authority may escalate such failure in accordance with this paragraph 6.

6.2 Where the Authority notifies the Supplier that a failure is to be escalated in accordance with this paragraph 6, in the first instance a meeting between the Supplier and Authority's authorised representatives shall be convened within seven (7) days of the date of the escalation notice to discuss the KPI failure and the reasons for such failure, and to agree a plan to resolve the failure (if still outstanding) and prevent any equivalent failure in the future.

6.3 Where such meeting does not result in a such a plan which is acceptable to the Authority, within four (4) days of such meeting, the Authority may escalate the failure to the Chief Executive Officers (or equivalent) of each Party to agree an appropriate plan.

6.4 Where the Chief Executive Officers (or equivalent) are unable, acting reasonably, to agree on actions specified in writing to resolve the failure (where still outstanding) and prevent any equivalent failure in the future within a further seven (7) days, the Authority shall be entitled to the remedy provided in paragraph 6.5.

6.5 Provided that paragraphs 6.1 through to 6.4 of this Schedule 6 have been complied with, where the Supplier:

6.5.1 **Redacted Under FOIA Section 43(2), Commercial Interests**; or

6.5.2 **Redacted Under FOIA Section 43(2), Commercial Interests**; or

6.5.3 **Redacted Under FOIA Section 43(2), Commercial Interests**; or

6.5.4 **Redacted Under FOIA Section 43(2), Commercial Interests**,

then, provided that the Supplier has still not agreed with the Authority on actions specified in writing to resolve the failure in accordance with paragraph 6.4, the Supplier shall be deemed to be in material breach of this Agreement and the Authority shall be entitled (in addition to any other remedy available to it under this Agreement) to: (i) terminate such outstanding elements of an Order which will not be delivered during the first twenty (20) weeks following the first delivery of Doses; or (ii) terminate this Agreement together with the outstanding elements of an Order which will not be delivered during the first twenty (20) weeks following the first delivery of Doses, in each case on fourteen (14) days written notice to the Supplier.

6.6 Worked examples of escalation are shown in Annex B of this Schedule 6.

Annex A

Examples related to the Pandemic stage KPIs, which are intended to aid understanding and do not vary the terms of the Agreement.

ASSUMPTIONS – example data

1. The Authority reserves sixty (60) million doses.
2. The price per dose is £6.35 excluding VAT.
3. At the time a Pandemic occurs the Authority orders fifty (50) million doses.
4. Doses invoiced and paid for by the Authority when all deliveries are complete is forty-five (45) million.

Based on the invoiced and paid doses the value of the Order in GBP is:	£ 285,750,000
The **maximum** Service Credit payable by the Supplier in this example is £285,750,000 x: **Redacted Under FOIA Section 43(2), Commercial Interests**	£ 14,287,500
Each Service Point has a nominal value in GBP of £285,750,000 x: **Redacted Under FOIA Section 43(2), Commercial Interests**	£ 14,288

Example 1

The Supplier fails to achieve Part A2 KPI 1 but meets all other KPIs to the end of the contracted delivery schedule. **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points are accrued and the Supplier repays to the Authority the sum of:	£ 2,143,125

(The calculation being **Redacted Under FOIA Section 43(2), Commercial Interests** *x £14,288)*

Example 2

The Supplier fails to meet Part A2 KPI 2 three weeks in a row.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points are accrued for the first failure which increases to **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points for the two subsequent occasions. The Supplier repays to the Authority the sum of:	£ 2,857,500

(The calculation being **Redacted Under FOIA Section 43(2), Commercial Interests** *x £14,288)*

Example 3

Greater than two percent (>**Redacted Under FOIA Section 43(2), Commercial Interests** 2%) of doses delivered in a calendar month are rejected by the Authority on two occasions. Service Points accrue for the first failure which increases to **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points for the second failure. The Supplier repays to the Authority the sum of:	£ 3,571,875

(The calculation being **Redacted Under FOIA Section 43(2), Commercial Interests** *x £14,288)*

Example 4

The Supplier fails to meet Part A2 KPI 4 by greater than seven (>7) weeks.

Redacted Under FOIA Section 43(2), Commercial Interests Service Points accrue to the Authority for

missing the five (5) week target and a further **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points accrue to the Authority for the failure exceeding the seven (7) week target. The Supplier repays to the Authority the sum of:

£ 714,375

(The calculation being **Redacted Under FOIA Section 43(2), Commercial Interests** *x £14,288.)*

Example 5

The Supplier reports are delivered more than five (>5) Business Days late for a six (6) week period. The reports are inaccurate for the six (6) week period as they contain two (2) errors. The Supplier repays to the Authority the sum of:

£ 2,057,400

(The calculation being **Redacted Under FOIA Section 43(2), Commercial Interests** *Service Points for each error,* **Redacted Under FOIA Section 43(2), Commercial Interests** *Service Points for not delivering the report on time and* **Redacted Under FOIA Section 43(2), Commercial Interests** *Service Points for being >5 days late for the first 4 weeks. (Equating to* **Redacted Under FOIA Section 43(2), Commercial Interests** *points per week for 4 weeks). For the next two weeks this increases to* **Redacted Under FOIA Section 43(2), Commercial Interests** *Service Points as* **Redacted Under FOIA Section 43(2), Commercial Interests** *Service Points have accrued in a 4 week period. (Equating to* **Redacted Under FOIA Section 43(2), Commercial Interests** *points a week for 2 weeks). The total for the 4 week period is* **Redacted Under FOIA Section 43(2), Commercial Interests** *Service Points and for the 2 week period is* **Redacted Under FOIA Section 43(2), Commercial Interests** *Service Points. The total sum to be repaid is therefore* **Redacted Under FOIA Section 43(2), Commercial Interests** *x £14,288)*

Annex B

Examples are intended to aid understanding and do not vary the terms of the Agreement.

ESCALATION

Escalation may occur as a result of the Supplier failing to achieve KPIs in accordance with Paragraph 6 of this Schedule 6.

Speed of escalation is a critical issue and to address this the circumstances and Service Points required for escalation have been designed accordingly.

Example 1

The Supplier fails to deliver any Product by the Initial Delivery Date. This will be escalated immediately as per Paragraph 6.1.2 of this Schedule 6.

Example 2

For a second week the aggregate volume of Product delivered by the Supplier falls below, its weekly report contains five (5) the **Redacted Under FOIA Section 43(2), Commercial Interests**; errors and is delivered greater than five (>5) Business Days late.

Under Part A2 KPI 2 the volume failure attracts **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points and under Part A2 KPI 5 weekly reporting attracts **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points.

Escalation will occur immediately as per Paragraph 6.1.4 of this Schedule 6.

Example 3

For a second week the aggregate volume of Product delivered by the Supplier falls the **Redacted Under FOIA Section 43(2), Commercial Interests**; which coincides with the first calendar month end when greater than two percent (>2%) of Product delivered has been rejected, the weekly report is delivered late and contains ten (10) errors.

Under Part A2 KPI 2 the volume failure attracts **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points, under Part A2 KPI 3 the Product rejection attracts **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points and under Part A2 KPI 5 weekly reporting attracts **Redacted Under FOIA Section 43(2), Commercial Interests** Service Points.

In this circumstance, the Supplier shall be considered to be in material breach of the agreement and the Authority may remedy the situation as per Paragraph 6.5.3 of this Schedule 6.

SCHEDULE 7

Manufacturing Facilities

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 8

Contract Management Part A

Key Contacts and Contract Review Meetings

The key contact details for both the Supplier and the Authority relating to the operation and management of this Agreement are set out at Annex A to this Schedule 8. The key contact details of a Party may be varied by that Party by notice in writing to the other Party.

A Contract Review Meeting between the representative(s) of the Authority and the Supplier will be held at least once every Quarter during each Preparedness Phase, save as agreed in writing between the Parties. The key contact details for both the Supplier and the Authority are set out at Annex A to this Schedule 8.

The Supplier shall provide a written report to the Authority at least two (2) weeks in advance of each Contract Review Meeting giving details of:

- Attendees - as a minimum attendees from the Supplier side shall be the contract manager, operations lead, scientific lead, and regulatory/quality lead or their designated substitutes, which designated substitutes must be approved by the Authority in advance of the Contract Review Meeting. The Authority attendees shall include the contract manager, commercial lead, operations lead and regulatory/quality lead;

- Pharmacovigilance;

- Current use of the Manufacturing Facilities, output from the Manufacturing Facilities relating to influenza vaccines and whether there are any current concerns regarding manufacturing operations such as lower than anticipated production rates;

- The testing of the Business Continuity Plan and its outcomes and any proposed or actual revisions to the Business Continuity Plan;

- Results from the handling and growing by the Supplier of emerging influenza viruses and the upper and lower limits of their growth;

- Licensing plan updates for extensions to the Marketing Authorisation, including clinical and non-clinical trial summary and scientific and technical developments relevant to product safety;

- Performance Monitoring Reports;

- An update on horizon scanning for emerging threats of potential Pandemic influenza strains;

- Current arrangements for stockpiling relevant materials;

- Current arrangements for procuring supplies that cannot be stockpiled;

- Current third party manufacturing contracts and their non-confidential

commercial terms (other than in respect of price) provided that details equivalent to those set out in Schedule 7 shall be non-confidential for these purposes;

- Any proposed changes to the Specification or Marketing Authorisation;
- Manufacturing Facility site changes relevant to the Supplier's obligations;
- Readiness of the Manufacturing Facilities utilised; licensing updates, regulatory inspections, schedules for planned shutdowns in such manufacturing facilities;
- Readiness on the equipment, components and raw materials;
- Management changes within the Supplier;
- Staff training and recruitment (including details of the turnover and retention of relevant staff) undertaken to meet Supplier's obligations;
- Any issues that have arisen and may impact upon Supplier performance;
- Any actual or potential impacts to the contractual requirements set out in this Agreement resulting from other Pandemic specific vaccine contracts with other countries that the Supplier has in place; and
- Any actual or potential impacts to the commitment in Clause 13.6.5 to reserve for the Authority, a percentage the **Redacted Under FOIA Section 43(2), Commercial Interests**;of its manufacturing capacity from the Manufacturing Facility.

Unless otherwise agreed between the Parties, the written report shall, where relevant, adopt the format set out at Annex B to this Schedule 8.

During the period from Alert stage C under the Revised WHO Classification System and throughout a Pandemic, the Parties will meet, unless otherwise mutually agreed, on at least a weekly basis (or more frequently where required by the Authority) with regard to updates on clinical trial requirements, including which virus strain would be used in the clinical trial.

In addition, during a Pandemic, the Parties will meet, unless otherwise mutually agreed, on a daily basis and shall meet every week in accordance with Clause 5.4.

Part B

Information to be included in a weekly report to be provided during a Pandemic

1. Initial yield estimates;
2. Forecasts regarding weekly capacity;
3. Bulk Vaccine:
    (i) Batch number;
    (ii) HA content per ml;
    (iii) Overage to be applied to the Batch for formulation and filling;
    (iv) Release status;
    (v) Theoretical yield of final formulated filled vaccine; and
    (vi) Comments.
4. Formulation:
    (i) Batch number;
    (ii) Manufacturing status (broken down by process stage); and
    (iii) Release status.
5. Finished vaccine:
    (i) Batch number;
    (ii) Total filled Doses;
    (iii) Doses assigned to the UK;
    (iv) Release status;
    (v) QP release date;
    (vi) Expiry date;
    (vii) Dispatch date;
    (viii) Pack size;
    (ix) Delivery date;
    (x) Comments; and
    (xi) Yield achieved.

6. A three (3) month rolling forward forecast of any additional capacity / Doses that are available to the Authority should the Authority require them. Such forecast: (i) will be provided for the purpose of visibility into the Supplier's manufacturing logistics and capacity and for information only; (ii) does not constitute any form of offer to supply the capacity set out in the forecast; (iii) does not constitute any form of indication on what the additional capacity may look like at any other point in time than when a particular forecast is made; and (iv) shall not constitute a commitment on what "Commercially Reasonable Endeavours" will entail in any particular circumstance. For the purpose of KPI 5 under Part A2 of Schedule 6, a good faith estimation at the point in time when the forecast is made shall be deemed to be one hundred percent (100%) accurate in respect of the forecast.

Schedule 8 Annex A - Key Contact Details

Authority Key Contacts	
Role	**Contact Name / Contact Details**
Redacted Under FOIA Section 40, Personal Information	**Redacted Under FOIA Section 40, Personal Information**
Redacted Under FOIA Section 40, Personal Information	**Redacted Under FOIA Section 40, Personal Information**
Redacted Under FOIA Section 40, Personal Information	**Redacted Under FOIA Section 40, Personal Information**
Supplier Key Contacts	
Role	**Contact Name / Contact Details**
Redacted Under FOIA Section 40, Personal Information	**Redacted Under FOIA Section 40, Personal Information**
Redacted Under FOIA Section 40, Personal Information	**Redacted Under FOIA Section 40, Personal Information**

Schedule 8 Annex B - Template Contract Review Meeting report

QUARTERLY PROGRESS REPORT – FORMAT

Company Name [xxxxx]
Date [xxxxx]
Prepared By [xxxxx]
Advanced Purchase Agreement for the Supply of Pandemic Specific Vaccine
Contract Reference Number:

1. Attendees

As a minimum, the progress meeting attendees from the

- *Supplier side shall include the contract manager, operations lead, scientific lead, and regulatory/quality lead, and*
- *Authority side shall include the contract manager, commercial lead, operations lead and regulatory/quality lead.*

2. Introduction

Executive summary of changes in progress since the last report.

3. Progress Report

3.1 Pharmacovigilance

Description of pharmacovigilance arrangements for the relevant portfolio vaccines.

a. Project progress and results.

b. Issues resolved.

c. Issues outstanding.

d. New issues.

3.2 Business Continuity Plan

Description of testing of the Business Continuity (BC) Plan, including IT BC with details of outcomes and any proposed or actual revisions.

a. Testing progress and results.

b. New issues and proposed/completed revisions.

3.3 Preparatory Activities

3.3.1 Stockpiling of relevant materials

Current arrangements for and progress in stockpiling relevant materials.

a. Issues completed.

b. Issues outstanding.

c. New issues.

3.3.2 Arrangements for procuring supplies that cannot be stockpiled

Current arrangements for procuring supplies that cannot be stockpiled.

a. Issues completed.

b. Issues outstanding.

c. New issues.

3.3.3 Third party contracts

Current third party pandemic supply contracts relating to the facilities for supply under this Agreement and their non-confidential commercial terms) other than in respect of price).

a. Issues resolved.

b. Issues outstanding.

c. New issues.

3.4 Changes to Product Specification or Marketing Authorisation

Details of any proposed changes to the product specification and details of progress in implementation. Progress report on variations to licenses that are relevant to the manufacture and supply of pandemic vaccine including timelines for approval by MHRA/EMA.

3.5 Manufacturing Facility Site Changes

Details of any manufacturing site changes relevant to the Supplier's obligations under this Agreement, including description of current use of manufacturing facilities, output from the Manufacturing Facilities relating to influenza vaccines and whether there are any current concerns regarding manufacturing operations such as lower than anticipated production rates.

a. Completed.

b. Outstanding.

c. New changes.

3.6 Readiness of critical equipment

a. Issues resolved.

b. Issues outstanding.

c. New issues.

3.7 Readiness of the manufacturing facilities; licensing updates, regulatory inspections (note if any critical/major observation), schedules for planned shutdowns in such manufacturing facilities

3.8 Change Management

Details of all major/critical changes with the Supplier.

a. Completed.

b. Outstanding.

c. New changes.

3.9 Staff (training and recruitment)

Details of any staff training and recruitment (including details of the turnover and retention of relevant staff) undertaken to meet Supplier's obligations.

3.10 Any issues that have arisen that may impact on Supplier performance

Details of any issues that have arisen that may affect Supplier performance.

4. Product Development Activities

Progress reports on activity in each of the following areas where applicable:

a. Clinical trial plans.

b. Investigations into product use in specific patient groups.

c. Studies with alternative virus strains with pandemic potential.

d. Stability studies.

e. Alternative potency assays.

f. Horizon scanning (including new and evolving vaccine technologies).

5. Key Performance Indicators

Information from the relevant Performance Monitoring reports.

6. Current use of manufacturing facilities

Description of current use of manufacturing facilities, output from the Manufacturing Facilities relating to influenza vaccines and whether there are any current concerns regarding manufacturing operations such as lower than anticipated production rates.

7. Surveillance of potential pandemic strains and impacts on preparedness

Detail of cases and activities undertaken in response to specific threats, such as the development of antigen for specific viruses that have pandemic potential.

8. Contractual impacts

Details of any actual or potential impacts to the contractual requirements set out in this Agreement resulting from other pandemic specific vaccine contracts with other countries that the Supplier has in place.

9. Current list of other Advance Purchase Agreements (APAs)

A current list of all other pandemic specific vaccine advance purchase agreements that the Supplier has in place with other countries in addition to the UK.

SCHEDULE 9

Supplier's Business Continuity Plan Summary

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 10

Change Control Process

1. DEFINITIONS

1.1 In this Schedule 10:

"Change Authorisation Note"	the form used by the Parties to set out the agreed Contract Change and which shall be substantially in the form of Appendix 3 to this Schedule 10;
"Change in Law"	any change in Law during the Term that either (a) relates to or is in respect of the development, manufacture, licensing, marketing and/or supply of pharmaceutical products, including without limitation the Product and influenza vaccine or (b) was the subject of consultation by the European Commission, a parliamentary green paper or parliamentary white paper prior to the Effective Date;
"Change Request"	a written request for a Contract Change which shall be substantially in the form of Appendix 1 to this Schedule 10;
"Contract Change"	any change to this Agreement other than, subject to paragraph 2.4 of this Schedule 10, a Change in Law;
"Fast-track Change"	any Contract Change which is expedited in a Pandemic in accordance with this Schedule 10;
"Impact Assessment"	an assessment of a Change Request substantially in the form of Appendix 2 to this Schedule 10;
"Receiving Party"	the Party which receives a proposed Contract Change; and
"Requesting Party"	the Party which requests a Contract Change.

2. GENERAL PRINCIPLES OF CHANGE CONTROL PROCESS

2.1. Subject to Clauses 27.1, 28.2, and 36.1, this schedule sets out the procedure for dealing with Contract Changes.

2.2. Under this Change Control Process:

2.2.1. either Party may request a Contract Change which they shall initiate by issuing a Change Request in accordance with paragraph 4;

2.2.2. the Supplier will assess and document the potential impact of a proposed Contract Change in accordance with paragraph 5 before the Contract Change can be either approved or implemented;

2.2.3. the Authority shall have the right to request amendments to a Change Request, approve it or reject it in the manner set out in paragraph 6;

2.2.4. the Supplier shall have the right to reject a Change Request solely in the manner set out in paragraph 7;

2.2.5. no proposed Contract Change shall be implemented by the Supplier until such time as a Change Authorisation Note has been signed and issued by the Authority in accordance with paragraph 6.2; and

2.2.6. during a Pandemic, a proposed Contract Change shall be processed in accordance with paragraph 8.

2.3. Until such time as a Change Authorisation Note has been signed and issued by the Authority in accordance with paragraph 9, then:

2.3.1. unless the Authority expressly agrees otherwise in writing, the Supplier shall continue to meet their obligations in accordance with the existing terms of the Agreement as if the proposed Contract Change did not apply; and

2.3.2. any discussions, negotiations or other communications which may take place between the Authority and the Supplier in connection with any proposed Contract Change, shall be without prejudice to each Party's other rights under this Agreement.

2.4. In the event that the Supplier's costs increase as a result of a Change in Law, or there is any other performance and/or pricing impact upon the Supplier arising from or relating to a Change in Law, the Supplier shall not be entitled to propose a Contract Change in respect of such costs increase or other impact. Any impact of a Change of Law shall be the responsibility of the Supplier and the Supplier shall ensure that it fully complies at all times with any such Change in Law. Notwithstanding the aforementioned, where any Change in Law necessitates other amendments to the terms of this Agreement, either Party may submit a Contract Change to implement any such necessary amendments.

3. COSTS

3.1. Subject to paragraph 3.2, each Party shall bear its own costs in relation to the preparation and agreement of each Change Request and Impact Assessment.

3.2. The Supplier will only be entitled to increase the Contract Price as a result of a Contract Change if it can demonstrate in the Impact Assessment that the proposed Contract Change requires additional resources and, in any event, any change to the Contract Price resulting from a Contract Change (whether the change will cause an increase or a decrease in the Contract Price) will be strictly proportionate to the increase or decrease in the level of resources required for the Supplier to perform its obligations under this Agreement as amended by the Contract Change.

3.3. Each Party's costs incurred in respect of any use of this Change Control Process

as a result of any error or default by the Supplier shall be paid for by the Supplier.

4. CHANGE REQUEST

4.1. Either Party may issue a Change Request to the other Party at any time during the Term of this Agreement.

4.2. If the Supplier issued the Change Request, then it shall also provide an Impact Assessment to the Authority as soon as is reasonably practicable but in any event within ten (10) Business Days of the date of issuing the Change Request.

4.3. If the Authority issued the Change Request, then the Supplier shall provide an Impact Assessment to the Authority as soon as is reasonably practicable but in any event within ten (10) Business Days of the date of receiving the Change Request from the Authority, provided that if the Supplier requires any clarifications in relation to the Change Request before it can deliver the Impact Assessment, then it will promptly notify the Authority in writing and the time period shall be extended by the time taken by the Authority to provide those clarifications. The Authority shall respond to the request for clarifications as soon as is reasonably practicable and the Supplier shall provide the Authority with sufficient information to enable it to understand fully the nature of the request for clarification.

5. IMPACT ASSESSMENT

5.1. Each Impact Assessment shall be completed in good faith and shall include (without limitation):

5.1.1. details of the proposed Contract Change including the reason for the Contract Change; and

5.1.2. details of the impact of the proposed Contract Change on the Supplier's obligations under this Agreement and any variation to the terms of the Agreement that will be required as a result of that impact.

5.2. Subject to the provisions of paragraph 5.3, the Authority shall review the Impact Assessment and, within fifteen (15) Business Days of receiving the Impact Assessment, it shall respond to the Supplier in accordance with paragraph 6.

5.3. If the Authority is the Receiving Party and the Authority reasonably considers that it requires further information regarding the proposed Contract Change so that it may properly evaluate the Change Request and the Impact Assessment, then within five (5) Business Days of receiving the Impact Assessment, it shall notify the Supplier in writing of this fact and detail the further information that it requires. The Supplier shall then re-issue the relevant Impact Assessment to the Authority within ten (10) Business Days of receiving such notification. At the Authority's discretion, the Parties may repeat the process described in this paragraph 5 until the Authority is satisfied that it has sufficient information to properly evaluate the Change Request and Impact Assessment.

6. AUTHORITY'S RIGHT OF APPROVAL

6.1. Within fifteen (15) Business Days of receiving the Impact Assessment from the Supplier or within ten (10) Business Days of receiving the further information that it may request pursuant to paragraph 5.3 above, the Authority shall evaluate the

Change Request and the Impact Assessment and shall do one of the following:

6.1.1. approve the proposed Contract Change, in which case the Parties shall follow the procedure set out in paragraph 6.2 below;

6.1.2. in its absolute discretion reject the Contract Change, in which case it shall notify the Supplier in writing of the rejection. The Authority shall not reject any proposed Contract Change to the extent that the Contract Change is necessary for the Supplier to comply with any changes in the Law applying to this Agreement other than a Change in Law. If the Authority does reject a Contract Change, then it shall explain its reasons in writing to the Supplier as soon as is reasonably practicable following such rejection; or

6.1.3. in the event that it reasonably believes that a Change Request or Impact Assessment contains errors or omissions, require the Supplier to modify the document accordingly, in which event the Supplier shall make such modifications within five (5) Business Days of such request. Subject to paragraph 5.3 above, on receiving the modified Change Request and/or Impact Assessment, the Authority shall approve or reject the proposed Contract Change within ten (10) Business Days.

6.2. If the Authority approves the proposed Contract Change pursuant to paragraph 6 and it has not been rejected by the Supplier in accordance with paragraph 7 below, then it shall inform the Supplier in writing and the Supplier shall prepare two copies of a Change Authorisation Note which it shall sign and deliver to the Authority for its signature. Following receipt by the Authority of the Change Authorisation Note, it shall sign both copies and return one copy to the Supplier. On the Authority's signature, the Change Authorisation Note shall constitute a binding variation to the Agreement provided that the Change Authorisation Note is signed by:

6.2.1. the appropriate person(s) specified in paragraph 9 of this schedule; and

6.2.2. the Authority within ten (10) Business Days of receiving the Supplier's signed copy. If the Authority does not sign the Change Authorisation Note within this time period, then the Supplier shall have the right to notify the Authority in writing and if the Authority does not sign the Change Authorisation Note within five (5) Business Days of the date of such notification, then the Supplier may refer the matter to the dispute resolution procedure under Clause 21.

7. SUPPLIER'S RIGHT OF APPROVAL

7.1. Following an Impact Assessment, if

7.1.1. the Supplier reasonably believes that any proposed Contract Change which is requested by the Authority:

7.1.1.1. would materially and adversely affect the risks to the health and safety of any person;

7.1.1.2. would require its obligations to be performed in a way that infringes any applicable Law; and/or

7.1.1.3. would (to implement) require either Party to possess legal powers or capacity that it does not have; or

7.1.2. the Authority is unwilling to accept the Impact Assessment provided by the Supplier in accordance with this Schedule 10,

then the Supplier shall be entitled to reject the proposed Contract Change and shall notify the Authority in writing of its reasons for doing so within five (5) Business Days after the date on which it is obliged to deliver the Impact Assessment in accordance with paragraph 4.3.

8. FAST-TRACK CHANGES

8.1. The Parties acknowledge that during a Pandemic it will be desirable to expedite the processes set out above.

8.2. During a Pandemic, the Parties shall use the process set out in paragraphs 3, 4, 5, 6 and 7 above but with reduced timescales, such that any period of fifteen (15) Business Days is reduced to three (3) Business Days, any period of ten (10) Business Days is reduced to two (2) Business Days and any period of five (5) Business Days is reduced to one (1) Business Day.

9. CHANGE AUTHORISATION

9.1. Any proposed Contract Change processed in accordance with this Schedule 10 will not be authorised and the Supplier shall not implement any proposed Contract Change until the Change Authorisation Note is signed and executed by the Authority's authorised signatory in accordance with the Authority's Contract Change authorisation and sign off procedure(s), as notified to the Supplier in writing from time to time.

Schedule 10 Appendix 1

Change Request Form

CR NO.:	TITLE:	TYPE OF CHANGE:
ACTION:	NAME:	DATE:
RAISED BY:		
AREA(S) IMPACTED:		
ASSIGNED FOR IMPACT ASSESSMENT BY:		
ASSIGNED FOR IMPACT ASSESSMENT TO:		
SUPPLIER REFERENCE NO.:		
FULL DESCRIPTION OF REQUESTED CONTRACT CHANGE:		
DETAILS OF ANY PROPOSED ALTERNATIVE SCENARIOS:		
REASONS FOR AND BENEFITS AND DISADVANTAGES OF REQUESTED CONTRACT CHANGE:		
SIGNATURE OF REQUESTING CHANGE OWNER:		
DATE OF REQUEST:		

Schedule 10 Appendix 2

Impact Assessment Form

CR NO.:	TITLE:	DATE RAISED:
DETAILED DESCRIPTION OF CONTRACT CHANGE FOR WHICH IMPACT ASSESSMENT IS BEING PREPARED AND DETAILS OF ANY RELATED CONTRACT CHANGES:		
PROPOSED ADJUSTMENT TO THE CONTRACT PRICE RESULTING FROM THE CONTRACT CHANGE:		
DETAILS OF PROPOSED ONE-OFF ADDITIONAL CONTRACT PRICE AND MEANS FOR DETERMINING THESE:		
DETAILS OF ANY PROPOSED CONTRACT AMENDMENTS:		
DETAILED RISK ASSESSMENT:		
RECOMMENDATIONS:		

Schedule 10 Appendix 3

Change Authorisation Note

CR NO.:	TITLE:	DATE RAISED:
DETAILED DESCRIPTION OF CONTRACT CHANGE FOR WHICH IMPACT ASSESSMENT IS BEING PREPARED AND DETAILS OF ANY RELATED CONTRACT CHANGES:		
PROPOSED ADJUSTMENT TO THE CONTRACT PRICE RESULTING FROM THE CONTRACT CHANGE:		
DETAILS OF PROPOSED ONE-OFF ADDITIONAL CONTRACT PRICE AND MEANS FOR DETERMINING THESE:		
SIGNED ON BEHALF OF THE AUTHORITY:	SIGNED ON BEHALF OF THE SUPPLIER:	
Signature:_____	Signature:_____	
Name:_____	Name:_____	
Position:_____	Position:_____	
Date:_____	Date:_____	

SCHEDULE 11

Provisions to apply on use of the Alternative Release Methodology

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 12

Delivery of Unlicensed Product

1. The provisions of this Schedule 12 shall only apply as set out in Clause 6.10. In this Schedule 12, unless the context dictates otherwise, a reference to "Product" shall be deemed to include a vaccine that the Supplier is still in the process of obtaining the Variation of the Marketing Authorisation for.

2. Prior to the Supplier obtaining the Variation of the Marketing Authorisation, the Authority shall be entitled on written notice to the Supplier to request that the Supplier deliver Product in advance of receipt of the Variation of the Marketing Authorisation.

3. The Agreement shall apply in its entirety to the supply and delivery of Product, save as varied in this Schedule 12.

4. The Product labels and patient information leaflets shall be fully in accordance with those specified in the Marketing Authorisation in respect of the Pandemic Preparedness Vaccine, save as to virus strain details or as otherwise agreed with the Licensing Authority and/or the Authority.

5. Should the Supplier manufacture unlicensed vaccine, when such Product is ready for delivery to the Authority, unless otherwise agreed in writing with the Authority, the Supplier shall arrange for the Product to be stored at a storage facility in the United Kingdom where the Supplier shall store the Product securely and in a good and proper manner and in accordance with any relevant requirements in the Summary of Product Characteristics until such time as the Authority requests in writing that such Product is delivered to the Authority prior to grant of the Variation of the Marketing Authorisation. During such storage, such Product shall be labelled in such a way that it is readily identified as Product ordered by and manufactured for the Authority, and shall be physically segregated from any other product stored at the storage facility. The Authority shall be entitled to inspect such Product in such storage facility at any time on reasonable notice to the Supplier. For the avoidance of doubt, title and risk relating to such Product shall remain with the Supplier, and the Authority shall have no obligation to pay for such Product and take title and risk of loss of the Product, until the earlier of: (i) delivery of such Product to the Authority following a written request by the Authority for the Supplier to deliver such Product to the Authority prior to the grant of the Variation of the Marketing Authorisation; or (ii) the grant of the Variation of the Marketing Authorisation and the delivery of the Product under Clause 6.

6. The Parties confirm and agree that should the Supplier manufacture unlicensed Product, and deliver such Product to the Authority following the grant of the Variation of the Marketing Authorisation, such Product shall be deemed to be fully licensed Product which is not then subject to this Schedule 12.

7. The Product will be delivered to the location specified in the Order only upon the completion of quality assessments and Batch release sample testing carried out by an OMCL and the issue of a written statement by that body that the Product meets the Supplier's Specification and is a suitable vaccine for use in a Pandemic.

The statement shall be as follows:

> "[*insert OMCL name*] has checked these batches for quality and potency and is satisfied that they comply with the manufacturer's product specifications. [*insert OMCL name*] cannot issue a formal release certificate because the product does not have a UK Marketing Authorisation. [insert OMCL name] considers that this vaccine is suitable for use on official government recommendation."

or words to the effect that the OMCL has verified that the Product has been produced in accordance with the manufacturer's product specification and is suitable for use on official government recommendation.

8. The Supplier shall apply to the appropriate regulatory body to supply the Product into the United Kingdom in accordance with the Human Medicines Regulations 2012 (SI 2012/1916).

9. In order for the Supplier to comply with its quality procedures and to allow delivery of unlicensed Product to the Authority's storage provider or distribution agent or Authorised Agent, the Supplier shall first need to audit such service provider. The Authority shall at the time of the award provide the Supplier with details of its current service providers and assist the Supplier in securing an audit of the service providers. In the event that the Authority's storage provider or distribution agent or Authorised Agent changes during the Term of this Agreement, the Authority shall notify the Supplier of such change and assist the Supplier in securing an audit of the new service provider.

10. There will be no use or administration of the Product unless both Parties have agreed on the relevant conditions governing such use.

SCHEDULE 13

Revised WHO Classification System (with alert sub-stages used in this Agreement)

Revised WHO Classification System with 'Alert sub-stages' used in this Agreement.

(1) Alert Classification		(2) Description of Phase (WHO terminology)	(3) Specific Criteria for Confirmation of Alert or Pandemic Phase
Interpandemic Phase		This is the period between influenza Pandemics	Not applicable
			Not applicable
Alert Phase	Alert Stage A Monitoring Stage*	This is the phase when influenza caused by a new subtype has been identified in humans. Increased vigilance and careful risk assessment at local, national and global levels are characteristic of this phase. If the risk assessments indicate that the new virus is not developing into a Pandemic strain, a de- escalation of activities towards those in the inter-Pandemic phase may occur.	1. Sporadic cases or small clusters in humans; 2. Human to human transmission, but not sustained; and 3. Potential for serious impact and illness
	Alert Stage B Preparation Stage*		1. Human to human transmission of flu virus able to sustain community outbreaks has been verified by WHO or national reference laboratories; 2. Potential for serious impact and illness confirmed; or 3. PHEIC declared by WHO
	Alert Stage C Pre-Pandemic Stage*		1. The same virus has caused sustained community level outbreaks in two or more countries as verified by WHO or national reference laboratories AND severity confirmed (>= CDC category 2); or 2. Declaration by EU Commission of public health emergency under Article 12 of Decision 1082/2013/EU

Pandemic Phase	This is the period of global spread of human influenza caused by a new subtype. Movement between the interpandemic, alert and Pandemic phases may occur quickly or gradually as indicated by the global risk assessment, principally based on virological, epidemiological and clinical data.	1. The same virus has caused sustained community level outbreaks in two or more countries in different WHO regions as verified by WHO or national reference laboratories AND severity confirmed (>= CDC category 2); or 2. Announcement by WHO of positive recommendation on whether and when to move production to Pandemic vaccine and the virus strain that should be used in the Pandemic vaccine.
Transition Phase	As the assessed global risk reduces, de- escalation of global actions may occur, and reduction in response activities or movement towards recovery actions by countries may be appropriate, according to their own risk assessments	1. Termination of PHEIC previously issued by WHO; 2. Modification or termination by WHO of temporary measures; 3. Termination by the EU Commission of public health emergency under Article 12 of Decision 1082/2013/EU; or 4. When both parties accept that the Pandemic virus strain has been included within normal seasonal production.
Interpandemic Phase	This is the period between influenza Pandemics	

* Alert Phase – the sub-phases A, B and C are not defined by WHO but on account of the encompassing nature of the Alert Phase, it is deemed appropriate to divide the Alert Phase into such sub-phases A, B and C.

Reference: World Health Organisation, 2017 Pandemic Influenza Risk Management Guidance Section 2.2 Pandemic Phases (p13).

SCHEDULE 14

Diversification

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 15

Management Information Schedule

This Schedule 15 contains a list of some of the information the Supplier is required to provide to the Authority under the Agreement. This Schedule 15 is intended as a summary and does not supersede the relevant provisions elsewhere in the Agreement.

Applicable clause/paragraph	Information to be provided	Frequency
Cl 3.3.3	In writing, the decision of the Licensing Authority following an application by the Supplier for a Variation of the Marketing Authorisation.	As soon as reasonably practicable following receipt of such decision.
Cl 3.4.1	In writing, the anticipated date of Seed Virus Receipt by the Supplier and receipt of the Reagent.	Within twenty-four (24) hours of being informed of such date in respect of each of the Seed Virus and the Reagent by the World Health Organization or a World Health Organization reference laboratory or a World Health Organization essential regulatory laboratory as appropriate.
Cl 3.4.2	In writing, the Seed Virus Receipt and the receipt of the Reagent.	Within twenty-four (24) hours of each of Seed Virus Receipt and receipt of the Reagent.
Cl 3.5	In writing the yield results of the Seed Virus and the results of the Reagent assay or Alternative Release Methodology.	As soon as each of them is available.
Cl 4.6	Delivery Schedule setting out the dates and quantity for delivery of the Product.	On or before the later of: **Redacted Under FOIA Section 43(2), Commercial Interests**
Cl 4.7	(Where the Supplier is obliged to provide the Delivery Schedule) An estimate of the dates and	Within **Redacted Under FOIA Section 43(2), Commercial Interests** of the date of an

	quantity for delivery of the Product based on the then available information on the likely Actual Yield.	Order.
Cl 5.11	An updated Delivery Schedule to reflect delivery of any additional Doses.	Promptly following a request by the Authority that the Supplier supplies additional Doses of the Product in excess of the Volume.
Cl 6.9	(Where the Product is unlicensed, and the Variation of Marketing Authorisation is subsequently granted) The patient information leaflets for the Product and any other relevant information from the Licensing Authority concerning the use or safety of the Product.	Within fourteen (14) days of the grant of such variation.
Cl 6.11	Notify in writing the grant of a New Marketing Authorisation.	Within twenty-four (24) hours of a New Marketing Authorisation being granted.
Cl 6.13	Progress in achieving the UK Manufacturing Capability.	Six (6) monthly intervals.
Cl 6.14	Formal final written notification the UK Manufacturing Capability is in place.	Promptly once UK Manufacturing Capability is in place, and written confirmation annually thereafter that the UK Manufacturing Capability remains in place.
Cl 7.16	Complete and accurate temperature records for each delivery of the Product.	Promptly following each delivery of Product.
Cl 8.12	Notification of a recall.	Promptly (taking into consideration the potential impact of the continued use of the Products on patients, service users and the Authority, as well as compliance by the Supplier with any regulatory

		requirements).
Cl 9.2	Summaries of its Business Continuity Plan, test reports and improvement plans. A copy of the Supplier's full Business Continuity Plan, test reports and improvement plans. Summary of any updated or revised Business Continuity Plan.	No less than once every twelve (12) months. Upon written request from the Authority. Within twenty-one (21) days of any material update.
Cl 10.5	Online report.	Weekly during a Pandemic.
Cl 11.2	In writing, if the Supplier knows or believes there to be any delay or other problem with the Marketing Authorisation or its renewal.	Within two (2) Business Days of becoming aware of the issue.
Cl 11.6.2	Notification of all data or information obtained by the Supplier relating to the safety and/or efficacy of the Product.	At all times.
Cl 11.6.3	In writing, inform and provide full details of any claim brought by any third party in relation to the Product.	Within seven (7) days of becoming aware.
Cl 11.6.4	Notification of actual or suspected adverse reaction to the Product which is not described in the Summary of Product Characteristics.	Within seven (7) days of becoming aware.
Cl 12.2.1	Notification of material change to Manufacturing Licence and all other licences necessary for manufacture of the Product.	Where such material change is to be made in the Preparedness Phase, in advance of its intention to implement such change. Where during a Pandemic, promptly.
Cl 13.1.3	Notification of material change to Yield Assumption information.	Promptly.

Cl 13.5.6	Any issue that impacts on ability to manufacture and supply Product during Preparedness Phase.	Within two (2) weeks of becoming aware.
Cl 13.7.1	Notification of an Occasion of Tax Non-Compliance.	Within five (5) Business Days of its occurrence.
Cl 14.14	Written report summarising all business transacted pursuant to this Agreement in the preceding twelve (12) months.	Within seven (7) days of each anniversary of the Effective Date.
Cl 20.5.1	Transfer any Request for Information.	Within five (5) Business Days of receiving a Request for Information.
Cl 20.5.2	(To the extent required by the applicable Law) Copy of all information in its possession or power in the form that the Authority or an Administering Entity or Devolved Administration requires.	Within five (5) Business Days of a request.
Cl 32.1.4	Reports on the information at Clause 32.1.3.	As reasonably specified by the Authority.
Cl 34.1	Reports confirming progress as against the Supplier's Social Value Commitments.	Quarterly (the first such report falling due three months following the Effective Date).
Sch 3	A report (in a format to be reasonably specified by the Authority from time to time) providing full pricing and costs transparency for each Quarter relating how the Pandemic Preparedness Fee has been calculated and used by the Supplier including all related costs incurred by the Supplier that make-up such fee and the cumulative level of any profit achieved by the Supplier relating to the Pandemic Preparedness Fee.	Quarterly (the first such report falling due three months following the Effective Date).

Sch 5 para 4	Full details of the volume of Product to be delivered and the dates for delivery of each shipment of Product.	In advance of delivery.
Sch 6 para 1.8	Operational risk and issues log, list of critical materials and their shelf life, preparedness dashboard, delivery schedule of stockpiled components.	Timely manner.
Sch 6 para 1.8	Update on progress to meeting UK Manufacturing Capability.	Quarterly.
Sch 6 para 1.8	Update on progress of research and development in new and/or improved vaccine production methods.	Quarterly.
Sch 6 para 1.8	Business continuity audit reports.	Quarterly with annual update.
Sch 6 para 1.8	Updates on Business Continuity Plan.	Annually.
Sch 6 para 1.8	Summary report on supply chain audits.	Annually.
Sch 6 para 1.8	Update on supply chain risk reduction plan.	Annually.

Sch 6 para 2.1	Performance Monitoring Report, containing the information: • the monitoring which has been performed and summary of any issues identified; • for each KPI, the actual performance achieved over the Reporting Period, and over the previous three (3) Reporting Periods; • a summary list of all failures to meet KPIs that occurred during the Reporting Period, together with details; • which KPI failures remain outstanding and progress in resolving them; • for any repeat failures, actions taken to resolve the underlying cause and prevent recurrence; • details of the Service Points which have accrued as a result of any KPI failures, and any earnback Service Points within the Reporting Period, indicating the failures to which the Service Points relate; • a rolling total of the number of KPI failures that have occurred and the amount of Service Points that have been incurred over the past twelve (12) Reporting Periods; • relevant particulars of any aspects of the performance which fail to meet the requirements of the Agreement; and • such other details as the Authority may reasonably require from time to time.	Within two (2) Business Days of the end of each week during a Pandemic following the Authority placing an Order, and Quarterly at all other times.
Sch 8 Part A	Written report (using the template provided in	At least two (2) weeks in advance of each Contract

	Schedule 8 Annex B) giving details of: • Contract Review Meeting attendees; • Pharmacovigilance; • the key performance information from the relevant Performance Monitoring Reports; • Current use of the Manufacturing Facilities, output from the Manufacturing Facilities relating to influenza vaccines and whether there are any current concerns regarding manufacturing operations such as lower than anticipated production rates; • The testing of the Business Continuity Plan and its outcomes and any proposed or actual revisions to the Business Continuity Plan; • Results from the handling and growing by the Supplier of emerging influenza viruses and the upper and lower limits of their growth; • Licensing plan updates for extensions to the Marketing Authorisation, including clinical and non-clinical trial summary and scientific and technical developments relevant to product safety; • Performance Monitoring Reports; • An update on horizon scanning for emerging threats of potential Pandemic influenza strains; • Current arrangements for stockpiling relevant materials; • Current arrangements for procuring supplies that cannot	Review Meeting.

	be stockpiled; • Current third party manufacturing contracts and their non-confidential commercial terms (other than in respect of price) provided that details equivalent to those set out in Schedule 7 shall be non-confidential for these purposes; • Any proposed changes to the Specification or Marketing Authorisation; • Manufacturing Facility site changes relevant to the Supplier's obligations; • Readiness of the Manufacturing Facilities utilised; licensing updates, regulatory inspections, schedules for planned shutdowns in such manufacturing facilities; • Readiness on the equipment, components and raw materials; • Management changes within the Supplier; • Staff training and recruitment (including details of the turnover and retention of relevant staff) undertaken to meet Supplier's obligations; • Any issues that have arisen and may impact upon Supplier performance; • Details of any actual or potential impacts to the contractual requirements set out in this Agreement resulting from other Pandemic specific vaccine contracts with other countries that the Supplier has in place; and • A current list of all other Pandemic specific vaccine advance purchase agreements that the Supplier has in place.	

Sch 16	Transparency Reports.	At the frequency set out in Schedule 16.

SCHEDULE 16

Transparency Reports

1 Transparency Reports

1.1 Within three (3) months of the Effective Date the Supplier shall provide to the Authority for its approval (such approval not to be unreasonably withheld or delayed) draft reports in accordance with Annex 1 (once approved, the "**Transparency Reports**").

1.2 If the Authority rejects any draft Transparency Report, the Supplier shall submit a revised version of the relevant report for further approval by the Authority within five (5) days of receipt of any notice of rejection, taking account of any recommendations for revision and improvement to the report provided by the Authority. If the Parties fail to agree on a draft Transparency Report the Authority shall determine what should be included.

1.3 The Supplier shall provide accurate and up-to-date versions of each Transparency Report to the Authority at the frequency referred to in Annex 1.

1.4 Any disagreement in connection with the preparation and/or approval of Transparency Reports, other than under paragraph 1.2 above in relation to the contents of a Transparency Report, shall be treated as a dispute.

1.5 The requirements for Transparency Reports are in addition to any other reporting requirements in this Agreement.

ANNEX 1: TRANSPARENCY REPORTS

TITLE	CONTENT	FORMAT	FREQUENCY
[Performance]			
[Contract Price]			
[Direct Sub-contractors]			
[Technical]			
[Performance management]			
[SME Management Information Reports]		[*In accordance with the Supply Chain Transparency Information Template below*]	[*Annually*]

SUPPLY CHAIN TRANSPARENCY INFORMATION TEMPLATE

	Financial Year 20[ ] ("Financial Year")	
	Under this Agreement	
	£	**%**
Estimated total contract revenue (£) to be received in this Financial Year	£[ ]	100%
Total value of Sub-contracted revenues (£) in this Financial Year under Sub-contracts with Material Sub-contractors and Direct Sub-contractors, other than Supplier's affiliates	£[ ]	[ ]
Total value of Sub-contracted revenues to SMEs (£) in this Financial Year under Sub-contracts with Material Sub-contractors and Direct Sub-contractors, other than Supplier's affiliates	£[ ]	[ ]
Total value of Sub-contracted revenues to VCSEs (£) in this Financial Year under Sub-contracts with Material Sub-contractors and Direct Sub-contractors, other than Supplier's affiliates	£[ ]	[ ]

	Financial Year 20[ ] ("Financial Year") ("Financial Year")	
	Supplier as a whole	
	£	%
Estimated total contract revenue (£) to be received in this Financial Year	£[ ]	100%
Total value of Sub-contracted revenues (£) in this Financial Year under Sub-contracts with Material Sub-contractors and Direct Sub-contractors, other than Supplier's affiliates	£[ ]	[ ]
Total value of Sub-contracted revenues to SMEs (£) in this Financial Year under Sub-contracts with Material Sub-contractors and Direct Sub-contractors, other than Supplier's affiliates	£[ ]	[ ]
Total value of Sub-contracted revenues to VCSEs (£) in this Financial Year under Sub-contracts with Material Sub-contractors and Direct Sub-contractors, other than Supplier's affiliates	£[ ]	[ ]

SUPPLY CHAIN TRANSPARENCY INFORMATION TEMPLATE

	Financial Year 20[ ]	
	Under this Agreement	
	£	**%**
Estimated total contract revenue (£) to be received in this Financial Year	£[ ]	100%
Total value of Sub-contracted revenues (£) in this Financial Year	£[ ]	[ ]
Total value of Sub-contracted revenues to SMEs (£) in this Financial Year	£[ ]	[ ]
Total value of Sub-contracted revenues to VCSEs (£) in this Financial Year	£[ ]	[ ]

	Financial Year 20[ ]	
	Supplier as a whole	
	£	**%**
Estimated total contract revenue (£) to be received in this Financial Year	£[ ]	100%
Total value of Sub-contracted revenues (£) in this Financial Year	£[ ]	[ ]
Total value of Sub-contracted revenues to SMEs (£) in this Financial Year	£[ ]	[ ]
Total value of Sub-contracted revenues to VCSEs (£) in this Financial Year	£[ ]	[ ]

SCHEDULE 17

Commercially Sensitive Information

Refer to:

Annex 10 - Confidential Information, submitted as part of the Supplier's ISOS Submission dated 20 June 2022

Annex 8 - Confidential Information, submitted as part of the Supplier's ISDS Submission dated 23 August 2022.

Annex 8 - Confidential Information, submitted as part of the Supplier's ITSFT Submission dated 2 November 2022.

Provided that it is agreed that the number of Doses awarded to the Supplier under this Agreement and the payment terms set out in this Agreement (but not the sums payable themselves) are in the public domain and are not therefore Commercially Sensitive Information.

Where entries in the three documents referred to in this Schedule 17 refer to a specific provision in this Agreement but are no longer relevant following agreed amendments to this Agreement following the date of the relevant submission, such entries shall no longer be applicable.

SCHEDULE 18

Material Sub-contractors

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 19

Social Value Commitments

Redacted Under FOIA Section 43(2), Commercial Interests